UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY d/b/a BLUE CROSS AND BLUE SHIELD OF LOUISIANA, HMO LOUISANA INC., DAVID MITCHELL, individually and on behalf of all others similarly situated, NEW YORK HOTEL TRADES COUNCIL & HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated, *and* CENTERWELL PHARMACY, INC.

Plaintiffs,

– *against* –

CELGENE CORPORATION, BRISTOL MYERS SQUIBB COMPANY, ANTHONY INSOGNA, *and* JEROME ZELDIS,

Defendants.

OPINION & ORDER

23-cv-7871 (ER)

RAMOS, D.J.:[1]

Plaintiffs Louisiana Health Service & Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana ("Louisiana Health"), HMO Louisiana, Inc., and David Mitchell (collectively, "Plaintiffs"), bring this putative class action against Celgene Corporation, Bristol Myers Squibb Company, Anthony Insogna, and Jerome Zeldis (collectively, "Defendants"), alleging unlawful monopolization under 15 U.S.C. § 2 and state law. Doc. 72. Additionally, Plaintiffs allege violations of consumer protection laws and unjust enrichment against Celgene. *Id.* Before the Court are three separate motions filed by Celgene, Insogna, and Zeldis, respectively, to dismiss the First Amended Complaint

[1] The Court provided this opinion to the parties in final form on April 1, 2025. Public filing of the opinion was delayed, however, in order to ensure that no confidential business information that had been filed under seal was released. Based on input from the parties, certain competitively sensitive information has been redacted from this opinion. *See generally FTC v. CCC Holdings Inc.*, 605 F. Supp. 2d 26, 30 n.1 (D.D.C. 2009) (describing similar procedure).

("FAC"). Docs. 108, 117, 120. For the reasons set forth below, Defendants' motions are GRANTED.

I. BACKGROUND

A. Overview

The following facts are based on the allegations in the FAC, which the Court accepts as true for purposes of the instant motion. *See*, *e.g.*, *Koch v. Christie's International PLC*, 699 F.3d 141, 145 (2d Cir. 2012).

Louisiana Health is a not-for-profit health insurance company that provides and manages the health benefits of more than one million members.[2] ¶ 6. HMO Louisiana, Inc. is a domestic health maintenance organization that is a wholly owned subsidiary of Louisiana Health. ¶ 7. David Mitchell is an individual living with multiple myeloma. ¶ 8. Plaintiffs are customers of pharmacies which initially purchased pomalidomide—a drug used in the treatment of multiple myeloma and sold under the brand name Pomalyst—from Celgene, or entities who reimbursed unspecified customers of such pharmacies. Doc. 109 at 22.

Bristol Myers Squibb Company and Celgene Corporation (collectively, "Celgene") are pharmaceutical companies that are organized and existing under the laws of the State of Delaware. ¶¶ 9, 10. In 2019, Celgene was acquired by Bristol Myers. ¶ 10. Celgene sells Pomalyst, a multi-billion dollar a year drug used to treat multiple myeloma. ¶ 1.

Insogna resides in San Diego, California, and is a partner at the law firm Jones Day. ¶ 11. Insogna has represented Celgene since 1996 and is alleged to have been directly involved in the procurement of certain fraudulently obtained patents. *Id.*

[2] Unless otherwise noted, citations to "¶ __" refer to the FAC.

Zeldis, M.D., PhD, resides in Hillsboro Beach, Florida,[3] and was a Celgene executive from 1997 to 2016. ¶ 12. During his tenure at Celgene, Zeldis served as Vice President of Medical Affairs, Chief Medical Officer, and CEO of Celgene Global Health. *Id*. Zeldis is alleged to have applied for, and obtained, some of the patents alleged in the complaint to have been fraudulently obtained. *Id.*

While employed by Celgene, Zeldis resided, owned a home, paid taxes, and maintained his vehicle registrations in New Jersey. Doc. 122 at ¶ 5. Additionally, he conducted all Celgene-related business in New Jersey. *Id.* at ¶ 6. From January 1995 to December 2003, Zeldis served as Clinical Associate Professor of Medicine at Cornell Medical School and owned a series of apartments in New York, initially purchased in 2008.[4] *Id.* at ¶¶ 2, 11. From 2008 until 2010, Zeldis rented his New York apartment to his daughter. *Id.* at ¶ 3. From 2010 until December 2011, it was being leased to renters, and from then until 2014, the apartment went "generally unoccupied," with Zeldis residing there for one to two weekends per month. *Id.* at ¶¶ 11–15.

Plaintiffs' main contention is that Celgene, along with outside patent counsel Insogna, and patent inventor Zeldis, unlawfully extended a monopoly in the market for Pomalyst. ¶ 1. According to Plaintiffs, Defendants accomplished this (i) through a pattern of fraud on the U.S. patent office, (ii) through a series of sham patent lawsuits against generic competitors looking to enter the market for Pomalyst, and (iii) by eventually resolving the sham lawsuits with settlements that delayed the entry of generic Pomalyst in the market for years, thereby protecting unlawful supra-competitive pricing. *Id.* The result, they contend, is that purchasers were overcharged—and continue to be

[3] The FAC alleges that Zeldis resides in Princeton, New Jersey, however, according to Zeldis' declaration, he relocated to Florida in 2016, following his retirement from Celgene. Doc. 122 at ¶ 7, 16.

[4] In 2008, Zeldis purchased an apartment in the Chelsea neighborhood of New York City. In 2014, he sold that apartment and purchased a second apartment in the same building. In 2020, he sold the second apartment and purchased a third apartment in the SoHo neighborhood of New York City, which he currently owns. Doc. 122 ¶¶11–17.

overcharged. ¶¶ 1, 374. The Court will first outline the regulatory background and then outline Plaintiffs' allegations in greater detail.

B. Regulatory Background

1. Hatch-Waxman

The manufacture and distribution of pharmaceutical drugs in the United States is regulated by the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. Recognizing that the Act's "cumbersome drug approval process delayed entry of relatively inexpensive generic drugs into the marketplace," *Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000), Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585, also known variously as the "Hatch-Waxman Act," "Hatch-Waxman Amendments," or "Hatch-Waxman." 21 U.S.C. § 355. Congress' intent was to balance the goal of incentivizing pharmaceutical investment and research, and "mak[ing] available more low cost generic drugs." *See* H.R. Rep. No. 98–857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48; H.R. Rep. No. 98–857, pt. 2, at 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2714. The Act seeks to accomplish this goal, in part, by encouraging "manufacturers of generic drugs . . . to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices." S. Rep. No. 107–167, at 4 (2001). The resulting regulatory framework has the following five relevant features.

First, a new "brand-name" drug must be approved by the Food and Drug Administration ("FDA") before it can be introduced. *See* 21 U.S.C. § 355(a). An applicant for such a drug must submit a New Drug Application ("NDA"), which requires the applicant to submit, among other things, "full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use," *id.* § 355(b)(1)(A)(i), as well as comprehensive information about the drug, *id.* §

355(b)(1). This reporting requirement entails "a long, comprehensive, and costly testing process." Federal Trade Commission v. Actavis, Inc., 570 U.S. 136, 142 (2013).

Second, once the FDA has approved a brand-name drug, a manufacturer of a generic drug may file an Abbreviated New Drug Application ("ANDA") specifying that the generic has the "same active ingredients as, and is biologically equivalent to," the already-approved brand-name drug. *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)); ¶ 20. In this way, the generic manufacturer can obtain approval while avoiding the "costly and time-consuming studies" needed to obtain approval "for a pioneer drug." *In re Revlimid & Thalomid Purchaser Antitrust Litigation*, No. 19-cv-7532 (ES) (MAH), 2024 WL 2861865, at *3 (D.N.J. June 6, 2024) (citing Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990)). An ANDA must rely on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand drug. ¶ 20. The FDCA and Hatch-Waxman operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. ¶ 22. The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, "speed[s] the introduction of low-cost generic drugs to market," thereby furthering drug competition. *Caraco*, 566 U.S. at 405.

Third, Hatch-Waxman "sets forth special procedures for identifying, and resolving, related patent disputes." Actavis, 570 U.S. at 143. "To facilitate the approval of generic drugs as soon as patents allow, Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents." *Caraco*,

566 U.S. at 405. "The statute mandates that a brand submit in its NDA 'the patent number and the expiration date of any patent which claims the drug for which the [brand] submitted the [NDA] or which claims a method of using such drug.'" *Id.* (citing 21 U.S.C. § 355(b)(1)). For example, if party "A" files an NDA for a brand product based on the drug "X," in that NDA application, A must list all of its patents that contain drug X. If the FDA approves the new drug, it publishes this information, without verification, in its "Orange Book."[5] *Caraco*, 566 U.S. at 405–06. In turn, any manufacturer filing an ANDA to produce a generic version of that pioneer drug must consult the Orange Book and "assure the FDA that [the] proposed generic drug will not infringe the brand's patents." *Id.* at 406. The generic can provide this assurance in one of several ways. *See* 21 U.S.C. § 355(j)(2)(A)(vii). Relevant here, the generic manufacturer may submit that assurance with a "paragraph IV certification," stating that the relevant listed patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug."[6] Id. § 355(j)(2)(A)(vii)(IV). But "[f]iling a paragraph IV certification means provoking litigation," Caraco, 566 U.S. at 407, because the patent statute treats such a filing as a *per se* act of infringement. *See* 35 U.S.C. § 271(e)(2)(A).

If the brand-name patentee brings an infringement suit within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the generic, usually for a 30-month period, until the earlier of (i) the passage of two-and-a-

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[5] The Orange Book, also known as the *Approved Drug Products with Therapeutic Equivalence Evaluations*, lists certain kinds of patents that the brand manufacturer of an FDA approved NDA asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. ¶ 18. Any exclusivities (or exclusive marketing rights) for new drugs are also listed in the Orange Book, alongside any applicable patents. ¶ 25.

[6] In order to obtain final FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. ¶ 29. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications: A paragraph I certification, indicating that no patent for the brand has been filed with the FDA; a paragraph II certification, indicating that any patent(s) for the brand has/have expired; a paragraph III certification, indicating that any patent(s) for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date; or a paragraph IV certification, indicating that any patent(s) for the brand is/are invalid or will not be infringed by the generic manufacturer's proposed product. *Id.*

half years or (ii) the parties litigate patent validity (or infringement) in court. *See Actavis*, 570 U.S. at 143. Until one of those conditions occurs, the FDA may only grant tentative approval, meaning the ANDA meets all regulatory requirements and is approvable but for the 30-month stay.[7] *Id.* Once the thirty-month stay ends, the FDA may grant an ANDA final approval if it meets all regulatory requirements. ¶ 31. At that point, the generic manufacturer may launch its product, even while the patent litigation is still pending, *i.e.*, an "at-risk" generic launch. *Id.* If it does so, the generic "risks" having to pay the brand manufacturer its lost profits if it launches its generic but loses the patent litigation. *Id.*

Fourth, to promote a balance between new drug innovation and generic drug competition, Hatch-Waxman also provides exclusivities for new drugs. ¶ 25. The FDA grants any such exclusivities upon approval of a drug if the sponsor or the drug meet the relevant statutory requirements. *Id.* Any such exclusivities for a drug are listed in the Orange Book, along with any applicable patents, and can run concurrently with the listed patents. *Id.* One such exclusivity, the five-year New Chemical Entity (NCE) exclusivity, applies to products containing chemical entities never previously approved by the FDA either alone or in combination. ¶ 26. During this period, no other drug using that chemical as an active ingredient can obtain FDA approval. *Id.* By combining the five-year NCE exclusivity period and the 30-month stay granted when the brand manufacturer brings an infringement suit within 45 days of receiving notification of the paragraph IV certification, the brand manufacturer can secure a maximum of seven and a half years of market exclusivity from the date of NDA approval. ¶ 26.

Fifth, "Hatch-Waxman provides a special incentive for a generic to be the first to file an [ANDA] taking the paragraph IV route." *Actavis*, 570 U.S. at 143. The first paragraph IV ANDA filer ("ANDA first filer") is granted a 180-day exclusivity period to market the generic version of the drug. *Id.*; *see* 21 U.S.C. § 355(j)(5)(B)(iii), (iv).

[7] FDA final approval may be delayed beyond the 30-month stay if the brand drug was entitled to other exclusivities. ¶ 30.

"During that period of exclusivity no other generic can compete with the brand-name drug." *Actavis*, 570 U.S. at 143–44. "If the [ANDA first filer] can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'" *Id.* at 144 (citing C. Scott Hemphill, *Paying for Delay Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)). "The 180-day exclusivity period, however, can belong only to the first generic to file.[8] Should that first-to-file generic forfeit the exclusivity right in one of the ways specified by statute, no other generic can obtain it." *Id.* (citing 21 U.S.C. § 355(j)(5)(D)). However, the brand-name manufacturer is not barred from entering the generic market with its own generic version of the drug—a so-called "authorized generic" or "AG"—during the 180-day exclusivity period. *Mylan Pharmaceutical Inc. v. FDA*, 454 F.3d 270, 276–77 (4th Cir. 2006); *Teva Pharmaceuticals Industry Ltd. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005); *see also Sanofi–Aventis v. Apotex Inc.*, 659 F.3d 1171, 1175 (Fed. Cir. 2011).

One way an ANDA first filer may forfeit its 180-day exclusivity is by failing to obtain tentative approval from the FDA within 30 months of the ANDA filing. ¶ 34. But failure to obtain tentative approval within the specified time period does not always result in in forfeiture. *Id*. The FDA will commonly defer a decision on forfeiture until it becomes necessary to decide the issue, typically when a later filer seeks final approval for its ANDA product. *Id*. At that time, the FDA must decide whether the ANDA first filer has forfeited, allowing for final approval of the subsequent filer's ANDA, or whether the first filer has not forfeited, postponing final approval for the subsequent ANDA first filer until expiration of the first filer's 180-day exclusivity period. *Id*.

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[8] In situations where the brand manufacturer has been granted NCE exclusivity, it is not uncommon to see multiple generics all file an ANDA on the first available date, as was done here. *See* ¶ 246. In such instances, they may all seek first-to-file status, with the potential for 180-day exclusivity so long as they obtain timely tentative or final drug approval. *See* ¶ 247.

Judicial and Administrative Scrutiny of Patents

The existence of one or more patents purporting to cover a drug product does not guarantee the patent holder a monopoly. ¶ 35. Patents can be invalidated or held unenforceable, either upon reexamination or in *inter partes* proceedings by the U.S. Patent and Trademark Office (PTO), by court decision, or by jury verdict. *Id*.

A generic can prevail in patent infringement litigation by showing that the patent holder cannot meet its burden of proving infringement. ¶ 36. Another is to show that the patent is invalid or unenforceable. *Id.* A patent is invalid or unenforceable when:

1. the disclosed invention is anticipated and/or obvious in light of earlier prior art;
2. its claims are indefinite, lack sufficient written description, or fail to properly enable the claimed invention;
3. an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material, or submits materially false information to the PTO during prosecution; or
4. when a later acquired patent is not patentably distinct from the invention claimed in an earlier patent, without exception.

¶ 37. An assessment of whether a patent is obvious and therefore invalid is based on the prior art that existed as of the priority date of the claimed invention. ¶ 38. "Prior art" refers to patents, published patent applications, and other non-patent sources, such as journal articles, that are publicly available. *Id*. The "priority date" may be the date of the application for the claimed invention, or it may be an earlier date if the current patent application is a continuation of an earlier one. *Id.* If the PTO rejects a patent application as obvious, a patent applicant may seek to overcome that rejection by submitting evidence that the claimed invention shows unexpected results, that is, that the claimed invention is at odds with what one would expect based on existing science. ¶ 39.

The patent examination process is conducted *ex parte*, with the patent examiner directly engaging in a dialogue with only the applicant. "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in

dealing with the PTO, which includes a duty to disclose to the PTO all information known to that individual to be material to patentability[.]" 37 C.F.R. § 1.56(a) (2012). For all documents submitted to the PTO, the applicant must certify that all statements from "the party's own knowledge" or "on information and belief" are true. 37 C.F.R. § 11.18(a)-(b) (2021). Additionally, the applicant must acknowledge that any statements made that "knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or knowingly and willfully makes any false, fictitious, or fraudulent statements or representations" will subject the applicant to penalties, including criminal penalties and "jeopardiz[e] the probative value" of the filing. 37 C.F.R. § 11.18(b) (2021).

2. Structure of the Generic Market

A generic drug may be either an "AB-rated" generic or an "authorized" generic. ¶¶ 50, 61. AB-rated generics are deemed by the FDA to be bioequivalent to the brand name drug. ¶¶ 22, 50. In a market without generics, a brand manufacturer has no FDA-approved bioequivalent substitutes and is thus a monopoly, *i.e.*, is able to control every sale of the product and can generate profits beyond the marginal cost of production by charging supra-competitive prices. ¶¶ 51, 60. This ability is what economist call market power. ¶ 51. According to the Plaintiffs, when an AB-rated generic enters the market, the brand manufacturer loses most of its unit sales to the generic, which can sell most of its units at a reduced price. ¶ 52. When multiple generics compete within the market, the increased competition further drives down the price, ending the brand manufacturer's initial monopoly and converting their former excess profits into "purchaser savings." *Id.* According to Plaintiffs, within a year of entry, generics can capture 90% of corresponding sales, with prices dropping by as much as 85%. ¶ 57. Under Hatch-Waxman, the first company that applies to produce an AB-rated generic by filing a paragraph IV certification receives the 180-day period of exclusivity described above, during which "no other generic can compete with the brand-name drug." *Actavis*, 570 U.S. at 143–44.

An authorized generic, or "AG," by contrast, is essentially a brand-name drug produced by a brand manufacturer but marketed under a generic label. ¶ 61; *Sanofi–Aventis*, 659 F.3d at 1174. Other than the fact that an AG does not have the brand name on its label, "it is chemically identical to the brand drug." ¶ 61. Unlike AB-rated generics, AGs are marketed and sold either by the brand manufacturer itself or another company with the brand company's permission. *Revlimid,* 2024 WL 2861865, at *4 (citing *Sanofi–Aventis*, 659 F.3d at 1174). AGs and AB-rated generics compete in the market for generics. *Id.*; ¶¶ 64, 65. The AG is unique in that it can compete with an AB-rated generic that is protected by Hatch-Waxman's 180-day period of exclusivity, even though other generics cannot. ¶ 62. AGs are thus the only potential source of generic price competition during the first-to-file generic manufacturer's 180-day exclusivity period. *Mylan Pharmaceuticals, Inc. v. U.S. Food and Drug Administration,* 454 F.3d 270, 276–77 (4th Cir. 2006).

C. Statement of Facts

1. Celgene's Alleged "Scheme"

Plaintiffs allege that Celgene fraudulently obtained certain patents covering Pomalyst in order to obtain monopoly power over the relevant market for that drug (the "*Walker Process* Fraud Allegations").[9] ¶ 1, 5, 46–87. Specifically, they allege that Celgene obtained the following patents fraudulently: (1) U.S. Patent Number 8,828,427, (the "'427 Patent"), U.S. Patent Number 9,993,467 (the "'467 Patent"), and U.S. Patent

[9] In *Walker Process,* the Supreme Court held that "the maintenance and enforcement of a patent obtained by fraud on the [PTO]" may form the basis of an action under Section 2 of the Sherman Act. *See Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 173–74 (1965). To plead a claim for relief under Section 2 of the Sherman Act on a *Walker Process* theory, a plaintiff must allege two conditions. "First, the plaintiff must show that the defendant procured the relevant patent by knowing and willful fraud on the [PTO] or (in the case of an assignee) that the defendant maintained and enforced the patent with knowledge of the fraudulent manner in which it was obtained." *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 506 (Fed. Cir. 2012). "Second, the plaintiff must prove all the elements otherwise necessary to establish a Sherman Act monopolization charge." *Ritz Camera & Image,* 700 F.3d at 506 (citations omitted).

No. 10,555,939 (the "'5939 Patent") [10], which cover the formulations for pomalidomide; (2) U.S. Patent No. 8,198,262, (the "'262 Patent"), U.S. Patent No. 8,673,939 (the "'3939 Patent"), and U.S. Patent No. 8,735,428 (the "'428 Patent"), which cover the methods of using pomalidomide to treat multiple myeloma; and (3) U.S. Patent No. 10,093,647, (the "'647 Patent"), U.S. Patent No. 10,093,648 (the "'648 Patent"), and U.S. Patent No. 10,093,649 (the "'649 Patent"), which cover polymorphic forms of pomalidomide.[11] ¶ 150–152, 201, 262. Plaintiffs allege that Celgene, as part of their overall "scheme," asserted those fraudulently obtained patents against its competitors through sham litigation to prevent competition, and then unlawfully settled with competitors in exchange for their delayed entry in the pomalidomide market.[12] ¶¶ 76–80, 87–89, 91–93. The simultaneously agreed upon delayed entry, they argue, will result in substantial damages in overcharges through at least early 2026. ¶¶ 374. The Court will outline the allegations related to these patents in turn.

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[10] The 10,555,939 patent is referred to as the '5939 patent, as there is a Celgene method of use patent, 8,673,939, which ends in the same three digits. ¶ 152 n. 65.

[11] Polymorphism refers to the ability of a chemical compound to crystallize into different three-dimensional crystal structures. ¶ 262 n. 89.

[12] As part of the larger "scheme," Plaintiffs assert that, though not the basis for their *Walker Process* Fraud Allegations, Celgene obtained and "bur[ied]" the patent portfolio of Dr. Robert D'Amato, a doctor at Boston Children's Hospital, which contained prior art over Celgene's later obtained method of use patents, claiming methods of using pomalidomide. Doc. 127 n. 79. According to Plaintiffs, beginning in 1993, Dr. D'Amato filed several patent applications disclosing thalidomide and its analogs, including pomalidomide, to treat diseases mediated by the growth of unwanted blood vessels associated with cancer and other conditions. ¶¶ 89–95. In December 1998, Children's Hospital partnered with EntreMed to begin developing these analogs into drugs. ¶¶ 110, 141. By 2002, D'Amato, Children's Hospital, and EntreMed had a portfolio of intellectual property and EntreMed planned to seek FDA-approval for a pomalidomide drug when Celgene allegedly interfered in the prosecution of D'Amato's patent applications and sued the PTO to stop it from issuing the patents. *Id*. Plaintiffs further allege that in November 2002, EntreMed sued Celgene for antitrust violations, which Celgene responded to by exclusively licensing D'Amato's 75+ patents and patent applications that claim, *e.g*., methods of using pomalidomide and other thalidomide analogs. ¶¶ 143–144, 181. Having obtained the patents, Celgene would later abandon them, allegedly to "manage the risk" these "almost-patents" posed to Celgene's ability to obtain later expiring pomalidomide method of use patents. ¶¶ 158, 143–144, 181; Doc. 127 at 4.

2. The Walker Process Fraud Allegations

Starting on August 19, 2008, Celgene would pursue nine patents with the PTO that Plaintiffs allege were either obtained through fraud or are otherwise invalid.[13] ¶¶ 149-99, 246. On February 8, 2013, the FDA first approved the marketing of pomalidomide, sold under the brand name Pomalyst, for 1–4 mg capsules. ¶¶ 1, 198. Pomalyst was approved as a new chemical entity, or NCE, which granted Celgene a 5-year exclusivity from generic entry in the pomalidomide market, until February 8, 2018. ¶¶ 199, 200, 246.

a. The Method of Treatment Patents

Plaintiffs allege that Celgene intentionally misrepresented and omitted material facts before the PTO to obtain the '262, '3939 and '428 patents, which cover methods for using pomalidomide to treat multiple myeloma. ¶ ¶ 150–152.

The '262 Patent

On August 19, 2008, Celgene applied for what would become the '262 patent. ¶ 163. Zeldis was the inventor and Insogna the prosecutor. *Id.* The patent examiner rejected the application because a combination of prior art references disclosed the cyclical treatment of multiple myeloma with pomalidomide, including the '517 patent[14] and Davies (2001)."[15] ¶¶ 121–123, 166. To overcome the rejection, according to Plaintiffs, Celgene misrepresented or omitted the truth about the '517 patent, Davies

[13] Plaintiffs allege that Defendants' efforts to fraudulently obtain patents began on November 6, 2002, with the filing of the provisional application number 60/424,600, which would eventually lead to the '262, '3939, and '428 method of treatment patents. ¶¶ 149–152. However, the 60/424,600 application is not at issue here. *Id.*

[14] On July 24, 1996, Celgene, the assignee, filed patent application number 08/690,258, which led to the 5,635,517 (the "'517 patent"). ¶ 97 n. 40. The '517 patent identified analogs of thalidomide, including lenalidomide and pomalidomide, as compounds decreasing TNFα levels, which constitutes a valuable therapeutic strategy for the treatment of many inflammatory, infectious, immunological[,] or malignant diseases . . . These include but are not limited to . . . cancer[.]" ¶ 97, 168.

[15] Davies (2001) is prior art research by Davies FE, that allegedly taught that immunomodulatory drugs, including pomalidomide, can be used to treat multiple myeloma and relapsed/refractory disease. ¶¶ 126, 175.

(2001), and "D'Amato (2001)."[16] ¶¶ 174–181. First, on December 23, 2010, Insogna attested, "[t]he PTO admits that the primary reference [the '517 patent] does not teach [pomalidomide]." ¶ 174. However, Celgene knew the '517 patent did teach pomalidomide because, for example, it was the foundational patent that claimed Celgene's profitable drug, Revlimid, the brand name for the drug compound lenalidomide, which is also used to treat multiple myeloma. ¶ 104; Doc. 127 at 4. Second, Celgene allegedly repeated the examiner's "mistaken belief" that Davies (2001) did not teach pomalidomide, by capitalizing on the confusion created by the article's use of immunomodulatory drugs ("IMiDs")—terminology coined by Celgene. ¶¶ 126, 175. Third, Celgene "misdirect[ed]" the examiner by arguing that the two patents the examiner cited, the '230 and '554, did not teach the use of pomalidomide to treat cancer, while concealing Davies (2001) and D'Amato (2001), studies that taught pomalidomide to treat multiple myeloma and other cancers. ¶¶ 175, 176, 178.

In August 2011, the examiner again rejected the '262 application. ¶ 185. The examiner concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to treat [multiple myeloma] with pomalidomide as suggested by "Kyle (2001)"[17] [,] Davies (2001), "Corral (1999)"[18] and "Muller (1999)"[19] [.]" *Id*. To overcome this rejection, according to Plaintiffs, Celgene made three more false misrepresentations or omissions. ¶¶ 187–188. First, Celgene stated "there is no suggestion in the cited art that pomalidomide is effective to treat multiple myeloma [.]" ¶ 187 n.72.

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[16] D'Amato (2001) is prior art research by D'Amato, that allegedly taught the specific thalidomide analog pomalidomide for the treatment of multiple myeloma. ¶ 131.

[17] Kyle (2001) is prior art research by Robert A. Kyle and others, which taught a method of treating multiple myeloma by administering thalidomide in combination with dexamethasone cyclically. ¶ 127.

[18] Corral (1999) is prior art research by L.G. Corral and others, which taught that pomalidomide is a more potent agent than other thalidomide analogs, with decreased potential for birth defects. ¶¶ 120, 254,

[19] Muller (1999) is prior art research by G.W. Muller and others, which disclosed the structure of pomalidomide and taught that "4-amino substituted analogs were found to be potent inhibitors of TNF-α." ¶ 120.

But D'Amato (2001), "Rogers (2001),"[20] "Rogers (2002),"[21] "Schey (April 2002),"[22] and "Schey (October 2002)"[23] all taught that pomalidomide is effective to treat multiple myeloma. ¶ 187. Second, Celgene suggested that the use of one thalidomide compound over another had not been publicly disclosed. ¶ 188. However, during reexamination of the '517 patent, Celgene submitted information to the PTO claiming that pomalidomide was 10,000 times more active than other compounds. *Id.* Third, Celgene misrepresented that treating cancer with pomalidomide by dosing cyclically was novel, when in fact, it was routine. ¶ 192; *see* Kyle (2001), "Coleman (2002),"[24] and "Cohen (1982)."[25] On April 9, 2012, the examiner issued the '262 patent. ¶ 192.

The '3939 & '428 Patents

On March 1, 2013, Celgene filed two additional applications for method-of-use patents regarding pomalidomide. ¶ 219. Like the '262 patent, both applications addressed the cyclical dosing of pomalidomide. ¶ 220. Again, Zeldis was the inventor. ¶ 219. In July 2013, the examiner rejected the applications as double patenting of the '262 patent and as obvious over the prior art, including Kyle (2001), Davies (2001), Corral

[20] Rogers (2001) is prior art research by Lentzsch S. Rogers and others, which disclosed that S-3-APG—pomalidomide—demonstrates superior *in vivo* anti-MM-activity compared to thalidomide and induces sustained complete tumor remission *in vivo*, without evidence of toxicity." ¶¶ 132, 133.

[21] Rogers (2002) taught that pomalidomide was able to directly inhibit the proliferation of myeloma and that pomalidomide is "a powerful anti-myeloma and anti-B-cell-lymphoma agent that has both antiproliferative and antiangiogenic effects." ¶ 134.

[22] Schey (April 2002) is prior art by S.A. Schey, which disclosed pomalidomide (referred to in the article as CC4047) for the treatment of multiple myeloma in humans. ¶ 135. Further, it disclosed "Phase I dose escalation study in relapsed/refractory multiple myeloma, designed to identify the maximum tolerated dose" and evaluate the safety when given orally for four weeks. *Id.* The established maximum tolerated dose was 5 mg/day. *Id.*

[23] Schey (October 2002) taught that pomalidomide could be effective at treating multiple myeloma at specific dosing amounts, up to a maximum tolerated dosing amount of 5 mg per day. ¶ 136.

[24] Coleman (2002) is prior art research by Coleman and others, which taught the specific amount of 40 mg of dexamethasone combined with thalidomide to treat multiple myeloma. ¶ 192.

[25] Cohen (1982) is prior art by Cohen and others, which taught the specific 28-day dosing cycle, *i.e.,* 21 days administration of an anticancer drug followed by 7 days of rest, in combination with dexamethasone. ¶ 192.

(1999), Muller (1999), and the '554 patent.[26] ¶ 222. To overcome the rejection, according to Plaintiffs, Celgene and Zeldis intentionally misrepresented or kept facts from the examiner. ¶ 226. Celgene filed a sworn declaration from its executive Dr. Anjan Thakurta, asserting that treating refractory or relapsed multiple myeloma with pomalidomide would have been surprising and unexpected. *Id.* However, using pomalidomide to treat refractory or relapsed multiple myeloma was known, and Celgene had already disclosed that pomalidomide was more potent than other thalidomide analogs. ¶ 227, 228. By the time of patenting, it would have been expected that myeloma patients who became resistant to the less potent thalidomide analog, *e.g.*, lenalidomide, could be treated with pomalidomide, a more potent thalidomide analog. *Id.* Celgene also made the same fraudulent misrepresentations and omissions as it had during the '262 patent prosecution, reinforcing the examiner's "mistaken belief" that: (1) the '517 patent does not teach pomalidomide; (2) D'Amato (2001) does not teach pomalidomide to treat multiple myeloma; and (3) Davies (2001) does not teach pomalidomide to treat multiple myeloma and relapse/refractory disease. ¶ 229. In reliance on Celgene and Zeldis' misrepresentations and omissions, according to Plaintiffs, the examiner issued the '3939 and '428 method of treatment patents on March 18, 2014 and May 27, 2014, respectively. ¶ 231.

b. The Formulation Patents

Similarly, Plaintiffs allege that Celgene intentionally misrepresented and omitted material facts before the PTO to obtain the '427, '467, and '5939 patents, which cover formulations of pomalidomide. ¶ 201.

[26] On February 12, 2001, Celgene filed a patent application, within the '517 patent family, that led to patent number 6,555,554 (the "'554 patent") which issued in 2003. ¶ 122. The '554 patent claimed methods of treatment involving lenalidomide to improve oncogenic or cancerous conditions and reduce TNFα, and disclosed pomalidomide in its methods of treatment claims. *Id.*

The '427 Patent

On May 19, 2010, Celgene and Insogna filed a patent application claiming an oral dosage form of a certain weight comprised of pomalidomide and a pharmaceutically acceptable carrier or excipient. ¶ 207. Plaintiffs suggest that this patent was basically a recipe: "combine pomalidomide with a few well-known carriers and excipients (such as mannitol, pregelatinized starch, and sodium stearyl fumarate) in specified ratios." Doc. 127 at 7. Both the instructions and ingredients had been known for years. *Id.* The examiner rejected the patent application multiple times for obviousness, including in light of studies, patents, and a textbook. ¶ 208. To overcome this rejection, Celgene and Insogna made false statements and omitted material information, including the fact that earlier studies, such as Schey (April 2002), disclosed the acceptable dosage amount for pomalidomide (up to 5mg/day). ¶¶ 204, 210.

After the examiner's second rejection, Celgene and Insogna filed the declaration of a Celgene scientist, Anthony Tutino, stating that many pomalidomide-excipient combinations he tested posed stability issues over time, but that the claimed invention did not. ¶ 213 Tutino stated that these were "unexpected results" supporting patentability. *Id.* But thalidomide and its analogs, according to Plaintiffs, are notoriously unstable; they degrade in the presence of water, a fact that had been well known and documented in the scientific community for decades. ¶ 214. It would have been routine to address this stability issue in the formulation process. ¶¶ 213, 214. Accordingly, there was nothing "unexpected." However, the examiner allowed the '427 formulation patent to issue. Doc. 127 at 7.

The '467 & '5939 Patents

On December 23, 2015, Celgene applied for a patent claiming formulations in terms of relative weight. ¶¶ 232–33. The named inventor on the patent application was Tutino. *Id.* The patent examiner repeatedly rejected the claims as obvious over the prior art. ¶ 234. In response, Celgene amended its claims requiring that the starch to mannitol

ratio be from 1:1 to 1:1.5 and submitted another allegedly fraudulent declaration by Tutino that claimed "surprising and unexpected" stability results. ¶ 241. According to Plaintiffs, Celgene's deception worked and on March 15, 2018, the examiner allowed the '467 formulation patent to issue, subject to a terminal disclaimer[27] as to the '427 patent. ¶ 242; Doc. 127 at 8.

On May 10, 2018, Celgene filed another application, for what would eventually lead to the '5939 patent, claiming slightly broader ranges of relative weight compared to the '467 patent. ¶¶ 267–68. The examiner rejected the application four times. ¶ 269. Celgene resubmitted the Tutino Declarations, again claiming "unexpected results." ¶ 270. According to Plaintiffs, the examiner was not fully convinced by the Tutino Declarations and only allowed the patent to issue subject to a terminal disclaimer, which required the patent term to end when the '427 and '467 patents expired. ¶¶ 242, 271. Further, they contend that the '5939 patent, which was nearly identical to the '467 patent, is invalid as obvious over the prior art and, as with the other formulation patents, was exceedingly easy to design around. ¶ 272.

c. The Polymorph Patents ('647, '648, and '649)

On December 20, 2017—approximately nine months after Celgene received seven paragraph IV certification letters describing the generic Pomalyst ANDA products in detail—Celgene filed three patent applications that would ultimately lead to the '647, '648, and '649 patents.[28] ¶¶ 262, 266, 282. They issued on October 9, 2018. ¶ 282.

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[27] A terminal disclaimer is when the inventor agrees to having a second patent terminate upon the expiration date of the first patent.

[28] Plaintiffs allege that at the time of the initial Complaint, at least nine generic ANDAs had been filed. ¶ 248. Celgene received paragraph IV certification letters from each as follows (listed in order of ANDA number): Teva (March 30, 2017), Natco and Breckinridge, who partnered in the creation of a Pomalyst ANDA (April 11, 2017), Apotex (March 30, 2017), Hetero (March 29, 2017), Par (April 12, 2017), Aurobindo (April 12, 2017), Mylan (April 6, 2017), Synthon and Alvogen, who partnered in the creation of a Pomalyst ANDA (May 4, 2018), and Dr. Reddy's Laboratories (May 31, 2019). ¶¶ 248, 267. Of the nine generic manufacturers, at least seven are first filers, *i.e.*, filed their ANDA on the first day, February 8, 2017, and are therefore eligible to enter the generic Pomalyst market with a 180-day exclusivity period, if approved. ¶ 247 n. 86. Synthon/Alvogen filed in 2018, while Dr. Reddy's filed in 2019. ¶¶ 247 n. 86, 276.

Each has a single independent claim, for a dihydrate, hemihydrate, or monohydrate form, respectively, identified by an x-ray powder diffraction pattern.[29] ¶ 264.

3. Sham Litigation

Plaintiffs allege that Celgene, having procured the above nine patents, knowingly filed four "waves" of sham lawsuits between May 4, 2017 and March 10, 2020, against all nine Pomalyst generics that submitted paragraph IV certification letters. ¶¶ 246, 273, 282, 293. They allege the lawsuits claimed infringement of the patents but were instead a tactic to prevent competition in the market for generic Pomalyst. *Id.*

In the first wave of "sham" lawsuits, beginning May 4, 2017, Celgene asserted the three pomalidomide method of treatment patents, the '262, '428, and '3939, and the only then existing formulation patent, the '427.[30] ¶¶ 250–251, 276–278, 286–288. According to Plaintiffs, no "reasonable pharmaceutical company in Celgene's position could [have] realistically expect[ed] to succeed on the merits of th[o]se lawsuits" because the method of treatment patents were obtained by fraud—as discussed above, obvious over prior art, and "in the case of at least the '427 patent, subject to non-infringement arguments." ¶¶ 251–257. There was no objective basis for asserting that the method of treatment patents were valid or that the defendants were infringing the patents because the prior art disclosed, *inter alia*: that thalidomide and its analogues could be used to overcome drug resistance of multiple myeloma cells; that thalidomide in combination with dexamethasone could be used to treat resistant multiple myeloma; the exact dosage for the thalidomide-dexamethasone mixture; that pomalidomide could be used to treat multiple myeloma; and that pomalidomide could be used to treat multiple myeloma and relapsed/resistant disease. ¶¶ 120, 124–129, 131, 133–137, 175, 254.

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[29] A hydrate is a compound containing water. Doc. 137 at 8 n. 37. The prefix indicates the number of water molecules to each molecule of water. *Id*.

[30] Celgene filed lawsuits against Par and Teva on May 4, 2017, and against Hetero, Aurobinodo, Apotex, Mylan, and Natco/Breckenridge on May 11, 2017. ¶ 250.

During the Spring of 2020, parties in the first wave of lawsuits were engaged in disputes regarding claims construction, *i.e.*, determining the definition of disputed patent terms. ¶ 297. Regarding the method of treatment patents, the parties disputed, *inter alia*, that a phrase in the claims' preamble, which stated that "[a] method of treating multiple myeloma" should be limitedly construed to require that the treatment of multiple myeloma be efficacious. ¶ 299. Counter to the generics, Celgene argued that the "[p]atentability of the claimed methods depends upon efficacy." *Hetero,* No. 17-3387 (D.N.J.), Celgene Opening *Markman* Brief, at 11. On June 16, 2020, the court issued its claim construction order, addressing four disputed terms in the three method of treatment patents (the '262, '428, and '3939) and the three formulation patents (the '427, '467, and '5939) (The "June 2020 Markman decision"). ¶ 298. The court sided with the generics, holding that "nothing in the claim language, the specification, or the prosecution history warrants reading into the claim an efficacy limitation based on the preamble." *Celgene,* No. 17-3387, 2020 WL 3249117, at *5.[31] Plaintiffs assert, "no reasonable pharmaceutical company in Celgene's position could have realistically expected to succeed on the merits," because "the patents were invalid [and] posed no impediment to generic entry." ¶ 302. Indeed, Plaintiffs assert that the June 2020 *Markman* decision, "eliminated any continued pretense that the [method of treatment patents] were valid." Doc. 127 at 25; *See Celgene v. Hetero*, No. 17-3387 (ES) (MAH), 2020 WL 3249117 (D.N.J.).

Additionally, Plaintiffs assert that the '427 formulation patent was similarly invalid as obvious over the prior art disclosures. ¶¶ 256, 266. "[T]he '427 is a simple patent claiming a finite combination of ingredients and weights" that "result [from] routine optimization" and are routinely designed around by generic companies. *Id.* Further, they argue, "Celgene had so little confidence in the '427 patent, it would end up

[31] Shortly after the court's *Markman* decision, the court granted generic Mylan's motion to dismiss the case for improper venue. *Celgene v. Mylan,* No. 19-cv-5802 (ES) (MAH), 2020 WL 12570814 (D.N.J. Sept. 25, 2020).

withdrawing its infringement claims as to this patent before most, if not all, of the settlements occurred." ¶¶ 256, 321.

In the second wave, between September 2018 and January 2019, Celgene filed six purportedly sham lawsuits against the generics related to the '467 formulation patent. ¶ 273. Similar to the '427 patent, in the opposition to the instant motion, Plaintiffs claim that the '467 patent was "obtained through fraud, invalid as obvious over the prior art, and easily designed around to avoid infringement." *Id.*; Doc. 127 at 25. Specifically, they assert that '467 was obtained through the fraudulent Tutino declarations—which would have been revealed during the patent litigation—and was so narrowly created and easy to design around that Celgene could not prove that any ANDA products would infringe it. ¶ 275.

Between February and April 2019, Celgene filed a third wave of six purportedly sham lawsuits related to the '647, '648, and '649 polymorphic patents. ¶ 282. First, Plaintiffs, in the opposition to the instant motion, assert that Celgene's claims had no colorable basis because the three patents were applied for *after* the generic companies had already developed their ANDA products and served paragraph IV certification letters to Celgene. ¶¶ 282–83; Doc. 127 at 25, 26. Additionally, no reasonable pharmaceutical company could expect to prevail on claims that the different Pomalyst ANDA products infringed one of the three crystal forms within the patents. ¶¶ 282–285. That is, in order to be successful against the generics in litigation regarding the polymorph patents, Celgene would be required "to establish that all nine ANDA products were a dihydrate, hemihydrate, or monohydrate exhibiting the same x-ray pattern diffraction pattern with the same peaks as those claimed in the patents." ¶ 284. This, Plaintiffs assert, they could not do. *Id.*

In March of 2020, Celgene filed a fourth wave of sham lawsuits regarding the '5939 formulation patent. ¶ 293. Plaintiffs allege that the '5939 patent—which is subject to terminal disclaimers as to the '427 and '467 formulation patents—is nearly identical to

the earlier formulation patents and is unenforceable for the same reasons. ¶¶ 271–72. That is, it was invalid as obvious over prior art, obtained by fraud, and could be easily designed around by savvy generics. *Id*.

According to Plaintiffs, Celgene achieved its objective in filing the sham lawsuits by creating an unwarranted delay in generic entry, *i.e.*, in addition to the NCE 5-year exclusivity, Celgene obtained a 30-month delay of FDA approval of the ANDAs, and ultimately obtained settlement agreements with all nine generics, further delaying entry into the market. ¶¶ 251, 257, 313, 366.

4. The Reverse Payment Allegations[32]

By the fall of 2020, Celgene was allegedly threatened with imminent generic entry for Pomalyst in the United States. ¶ 305. First, the FDA was no longer barred from granting ANDA final approval to the ANDA first filers since both the NCE exclusivity period and the 30-month litigation stay had expired on February 8, 2017, and August 8, 2020, respectively. ¶¶ 306, 307. On October 30, 2020, the FDA granted final approval to the Aurobindo and Natco/Breckenridge ANDAs,[33] ending any FDA-imposed regulatory barriers preventing them from immediately launching their generic product.[34] ¶ 309. Finally, Plaintiffs assert that Celgene was confronted with the fact that their Pomalyst patents were likely to be held invalid and not infringed by the Pomalyst ANDA first filers in the pending lawsuits because they were fraudulently obtained. ¶ 310. Rather than

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[32] A typical reverse payment happens when: "Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars." *Actavis*, 570 U.S. at 140. Such agreements may be unlawful because two competitors agree not to compete and thereby unlawfully and unreasonably allocate market power. *In re Revlimid*, No. CV 19-7532 (ES) (MAH), 2024 WL 2861865, at *7. A reverse payment need not necessarily be in cash form. *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 403–09 (3d Cir. 2015). An agreement may still be an unlawful "reverse payment" where it involves an unexplained large transfer of value from the patent holder to the alleged infringer. *Id.* at 409.

[33] Teva was granted final FDA approval of their Pomalyst ANDA on May 4, 2022. ¶ 351.

[34] At the time of the settlement agreements, it was unclear whether these generics would be entitled to the 180-day exclusivity period: Aurobindo and Natco/Breckenridge had failed to get tentative approval within 30 months of filing its ANDA, potentially jeopardizing their 180-day exclusivity period. ¶ 309 n. 97.

allow generic entry, starting in November 2020, Celgene began entering into settlement agreements with generics, allegedly with reverse payments "to pay off its would-be Pomalyst competitors to have them delay generic entry for approximately six years, until early 2026." ¶ 313.

Pomalyst Settlement Agreements

The FAC alleges facts regarding the agreements to settle then-pending Pomalyst patent lawsuits between Celgene and three ANDA first filers, Natco/Breckinridge, Teva, and Aurobindo. ¶¶ 313–363. Celgene entered into the agreements with Natco/Breckinridge (the "Celgene-Natco/Breckinridge Agreement") in November 2020, Teva (the "Celgene-Teva Agreement") in March 2021, and Aurobindo (the "Celgene-Aurobindo Agreement") on July 16, 2021. ¶¶ 346, 353. "The terms of th[ose] arrangement[s] were in part reflected in documentation, but also by the combined *de facto* economics of the industry and incentives created by the agreement." ¶¶ 315, 346, 355. Specifically, the FAC alleges that in exchange for simultaneously timed generic entry in the market for Pomalyst in early 2026 by the Pomalyst ANDA first filers, the settlement agreements included terms that provided for large, unjustified payments. ¶¶ 316–327, 346–363. These payments consist of a monopoly profit share from a separate, unlawfully allocated market regarding another Celgene drug, Revlimid, as well as most favored entry clauses and contractually granted exclusivity rights in the generic Pomalyst market. *Id*.

In addition, according to the FAC, all Pomalyst ANDA first filers, or their partner, had a volume-limited license[35] for generic Revlimid.[36] ¶¶ 325, 327, 349, 360. In 2015,

[35] A volume-limited license is a licensing agreement where a company is allowed to manufacture and sell their generic at a limited quantity or volume prior to the patent's expiration. ¶ 325.

[36] Par, which withdrew its paragraph IV certification letter, is the only Pomalyst ANDA first filer without a volume-limited license for generic Revlimid. ¶ 343. In their consolidated opposition to the instant motions, Plaintiffs assert that based on based on publicly provided data: Natco—which would later partner with Breckinridge to create a Pomalyst ANDA product— partnered with generic manufacturers Allergen and Teva for a Revlimid generic; Alvogen partnered with generic manufacturer Lotus; and it appears that generic manufacturer Hetero's wholly owned subsidiary, Camber, was party to the Revlimid limited-volume license. Doc. 127 at 11 n. 50.

Celgene and Natco settled patent litigation over Natco's, and then partner Teva's, proposed generic for Revlimid through an agreement explicitly containing market allocation arrangements. ¶ 325. There, Celgene and Natco allocated the Revlimid market by agreeing to have Natco delay all generic entry until 2022. *Id.* Beginning in March 2022, Natco could sell a "mid-single-digit percentage of the total lenalidomide capsules dispensed in the United States during the first full year of entry." *Id.* That "volume limitation is expected to increase gradually each 12 months until March of 2025" but is "not expected to exceed one-third of the total lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license under this agreement." *Id.* In that arrangement, the royalty free volume caps would expire in January 2026. *Id.* According to Plaintiffs, the volume-limited license agreements significantly reduce the extent of the price reduction and effectively allocate the market amongst competitors, and thus constitute a "reverse payment." ¶ 327.

Plaintiffs assert that both by design and effect, the Celgene and Natco arrangements delayed generic entry in the market for Revlimid until 2022 and will maintain supra-competitive pricing of Revlimid until the first quarter of 2026. ¶ 325. In exchange, the same generics, in the market for Pomalyst, would delay generic entry until the same time. ¶¶ 325, 327, 349, 360; Doc. 127 at 11. Plaintiffs assert that Celgene entered into similar arrangements with the other Pomalyst ANDA first filers. *Id*.

Additionally, the FAC alleges that the Pomalyst agreements between Celgene and each of Natco/Breckenridge, Teva, and Aurobindo included most-favored entry clauses ("MFE") to coordinate entry dates amongst would-be generic entrants. ¶¶ 325, 326. An MFE, or acceleration clause, allows a generic manufacturer to enter the market earlier than the originally agreed upon entry date if another ANDA first filer enters earlier or if a non-settling generic is successful in invalidating Celgene's unexpired patents. *See Revlimid,* 2024 WL 2861865, at *8; Doc. 127 at 11, 12. The Pomalyst agreements with Natco/Breckinridge, Teva, and Aurobindo are each allowed pre-expiration use of

Celgene's patents beginning in [redacted], respectively. ¶¶ 314, 346, 353. Due to the MFE provisions, each of these generics are allowed pre-expiration use of Celgene's patents no later than the earliest of these dates, *i.e.*, [redacted]. *See* ¶¶ 355–556. According to the FAC, MFE clauses constitute reverse payments to the settling generics because they deter other generics from continuing to challenge Celgene's patents and provides assurance to Natco/Breckinridge, Teva, and Aurobindo that they would receive the most favorable entry date and retain its lucrative exclusivity period.[37] ¶¶ 325–26.

Finally, the FAC alleges that the Pomalyst agreements with Natco/Breckenridge, Teva, and Aurobindo included terms that essentially "resurrected" the 180-day exclusivity period that those ANDA first filers were allegedly at risk of forfeiting. ¶¶ 290–292, 316, 356, 359. In order to avoid forfeiture of the 180-day exclusivity granted to ANDA first filers, the seven generic companies that had filed their ANDAs on February 8, 2017, were required to obtain tentative or final approval of their application from the FDA by August 8, 2019.[38] ¶ 290. However, none had obtained approval by that date. ¶ 291. According to the FAC, the FDA noted in its regulatory findings that the seven first filers had failed to obtain approvals, but that they would defer any determination regarding a final decision until it became necessary to decide the issue, which is commonly done. *Id;* ¶ 34. As a result, according to Plaintiffs, "all of the first filing generics were at significant risk of having forfeited their 180-day exclusivity." ¶ 292. To

[37] In their opposition to the instant motion, Plaintiffs assert, for the first time, that the Pomalyst settlements contained most favored entry plus ("MFEP") clauses. Doc. 127 at 30, 31. An MFEP clause provides "that the brand manufacturer will not grant a license to any second filer to enter the market until a defined period of time after the first filer enters." *Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 590 (N.D. Cal. 2020). In the FAC, Plaintiffs do not cite any specific settlement provisions regarding either the alleged MFE or MFEP clauses. However, [redacted] together, provide that if another ANDA first filer is permitted to market generic Pomalyst before [redacted] *See* Doc. 111-1 at 26, 31, *see also* Docs. 111-2 at 21, 25; 111-3 at 20, 21, 26.

[38] The FDA granted 180-day exclusivity to the ANDA first filers Teva, Natco/Breckenridge, Apotex, Hetero, Par, Aurobindo, and Mylan. ¶ 290.

remove this risk, Celgene allegedly granted the seven first filers a 180-day exclusivity period in their settlement agreements, which "conveyed tremendous value." Doc. 127 at 11, 12.

Payment Valuation

According to the FAC, the value of the settlement payments that Celgene made to Natco/Breckinridge, Teva, and Aurobindo were "magnitudes" larger than Celgene's avoided litigation expenses, and likely well into the nine figures." ¶¶ 338, 340, 341, 344, 347, 357. In describing the Celgene-Natco/Breckinridge agreement, for example, the FAC asserts that the three components of the reverse payments, *i.e.*, the protection of profit shares in the Revlimid market, the MFE clause, and the resurrected 180-day exclusivity, from Celgene to Natco/Breckinridge, are valued at between approximately $150 to $300 million. ¶¶ 338, 340, 341, 344. Plaintiffs calculate this as follows:

> "Under normal market conditions, after several months of *bona fide* generic entry, the generic penetration rate is typically 90%. If the only ANDA generic to enter the market was Natco/Breckenridge, [they] would expect to take roughly half of these generic sales, [assuming the other half went to an AG.] Facing competition from the brand manufacturer and the [AG], the generic product is typically priced at approximately 60% of the brand price. Applying those figures to the [Pomalyst] market, during the first six months, a generic company with [180-day] exclusivity would expect sales of about $300 million ($2.25 billion in 2021 U.S. sales x 0.5 years x 90% of the market is generic x 50% of generic market x 60% price of the brand)." ¶ 339. [Adding Aurobindo to the market], the revenues from the generic products would now be divided by a third each [.][39] In addition, the presence of an additional generic would likely have caused some degree of additional price erosion. *Id.* However, each of the ANDA [first] filers would still expect to earn about $167 million ($2.25 billion in 2021 U.S. sales x 0.5 years x 90% of the market is generic x 33% of generic market x 50% price of the brand). ¶ 340. "As a result, a reasonable company in the position of Natco/Breckenridge in November 2020, [] would expect to achieve about $167 to $300 million in revenues over six months

[39] The FAC references Aurobindo, in addition to Natco/Breckinridge, because they were the only two Pomalyst ANDA first filers with final ANDA approvals as of October 30, 2020. ¶¶ 309, 372, 373.

> were it to launch generic [Pomalyst] and exploit a period of oligopolistic pricing."[40] ¶ 341.

In contrast, Plaintiffs calculate that Natco/Breckinridge would expect to achieve only approximately $19.4 million over six months[41] by agreeing to delay entry until early 2026, per the settlement agreement, and entering a fully genericized Pomalyst market. ¶¶ 342–43.

In exchange for the reverse payments, Plaintiffs allege that the ANDA first filers allegedly agreed to delay entry of their Pomalyst generics until "early 2026." ¶¶ 332–333, 342–43, 346, 349–50, 354, 364–366, 370–71. However, according to Plaintiffs, absent Celgene's anticompetitive conduct, they would have launched as early as October 30, 2020. ¶¶ 361–73, 407, 411. Specifically, Plaintiffs assert that "absent the Pomalyst agreements, and under competitive conditions, a reasonable generic company . . . would have (i) launched generic Pomalyst after prevailing at trial, (ii) launched at risk at some point after obtaining final approval, or (iii) entered into an arm's length, payment-free agreement that provides for unrestricted sales and/or an earlier, risk-adjusted, agreed entry date." ¶ 373. Celgene, by unlawfully extending its monopoly in the market for Pomalyst until early 2026, has "forced [Plaintiffs] to purchase brand Pomalyst at supra-competitive prices through at least that time." ¶ 370.

D. Procedural Background

The Complaint was filed on September 5, 2023, against Celgene, Bristol Myers, Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, Eugia Pharma Specialties Limited, Breckenridge Pharmaceutical, Inc., Natco Pharma Limited,

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[40] According to the FAC, an ANDA first filer with final FDA approval may launch its product "at-risk," even if the patent litigation is still pending. ¶ 31. The "risk" being that the generic manufacturer will have to compensate the brand manufacturer for any lost profits from the at-risk launch if the generic ultimately loses the patent litigation. *Id.* However, the FAC asserts that the generic is highly incentivized to launch at-risk where it expects to ultimately prevail in the patent litigation. *Id.*

[41] The $19.4 million of profits generated by Natco/Breckinridge over the 180-day exclusivity period in the settlement agreement is calculated as follows: "Projected $3.02 billion in 2026 U.S. sales x 0.5 years x 90% of the market is generic x 0.143 (*i.e.*, $1/7^{th}$ of the generic market^{100}) x 10% of the brand)," assuming full Pomalyst ANDA first filer entry. ¶ 361.

Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Limited. Doc. 1. It alleged six counts: Counts I, III, and VI were against Celgene and Bristol Myers for (1) unlawful monopolization in violation of 15 U.S.C. § 1, (2) monopolization under state law, and (3) unjust enrichment under state law. *Id.* at 103, 106, 117. Counts II, IV, and V were brought against all defendants for (1) contract, combination, or conspiracy in restraint of trade in violation of 15 U.S.C. § 1, (2) contract, combination, or conspiracy to restrain trade under state law, and (3) violations of state consumer protection laws, respectively. *Id.* at 105, 110, 113.

On December 19, 2023, Plaintiffs filed the FAC, alleging six counts: Counts II, III, and VI are against Celgene and Bristol Myers for (1) monopolization under state law, (2) violations of state consumer protection laws, and (3) unjust enrichment under state law, respectively. Doc. 72 at ¶¶ 415–445, 473–695. Count I, IV, and V are brought against all remaining Defendants for unlawful monopolization in violation of 15 U.S.C. § 1 and state law. *Id.* at ¶¶ 403–414, 446–472.[42]

On March 21, 2024, Defendants Celgene, Insogna, and Zeldis filed separate motions to dismiss the FAC. Docs. 108, 117, 120. Celgene alleges that Plaintiffs have failed to plausibly plead (1) an anticompetitive reverse payment, (2) *Walker Process* fraud on the PTO office, and (3) sham litigation.[43] Docs. 109 at 6, 25, 43; 129 at 2, 13, 16. Insogna alleges that Plaintiffs (1) have failed to state a claim pursuant to Section 2 of the Sherman Act, (2) have failed to state a claim for monopolization pursuant to state law,

[42] On October 2, 2024, Plaintiffs voluntarily dismissed defendants Teva Pharmaceuticals USA and Teva Pharmaceutical Industries Limited. On October 19, 2024, Plaintiffs voluntarily dismissed defendants Natco Pharma Limited, Breckenridge Pharmaceutical, Inc., and Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Eugia Pharma Specialties Limited. Docs. 73–75, 78–80. On that same day, October 19, 2024, they amended the complaint to include defendants Anthony Insogna and Jerome Zeldis. Doc. 72.

[43] After the filing of the instant motions to dismiss the FAC, *New York Hotel Trades Council & Hotel Association Of New York City, Inc., Health Benefits Fund v. Celgene Corp., Bristol Myers Squibb Co., Anthony Insogna, and Jerome Zeldis*, 24-cv-02230 and *Centerwell Pharmacy, Inc. V. Celgene Corp. & Bristol Myers Squibb Co.*, 24-cv-06924 were consolidated with this case. Docs. 124, 150. The consolidated plaintiffs are not parties to the instant motions.

and (3) are time-barred from pursing their claims. Docs. 118 at 6, 16, 17; 130. Zeldis alleges that Plaintiffs have (1) failed to plausibly plead that the Court has personal jurisdiction over him, (2) failed to state a claim pursuant to Section 2 of the Sherman Act, (3) failed to state a claim for monopolization pursuant to state law, and (4) are time-barred from pursing their claims. Docs. 121 at 5, 11, 13, 14; 131. Notices of supplemental authority were filed with the Court by Celgene and Plaintiffs, Docs. 134, 135, 140, 145, 148, 149, after the briefing was completed on Defendants' motions to dismiss.

On April 18, 2024, Plaintiffs requested that Zeldis' motion be held in abeyance so that they could seek limited jurisdictional discovery from him. Doc. 126. On May 8, 2024, Plaintiffs filed a letter motion requesting a conference for leave to serve jurisdictional discovery. Doc. 132. The Court held a pre-motion conference on May 31, 2024, where Zeldis was directed to submit supplemental letter briefing by Monday, June 3, 2024, with Plaintiffs' response due by Tuesday, June 4, 2024.[44] In a July 9, 2024 Order, the Court denied Plaintiffs' request for jurisdictional discovery, holding that their allegations are based "on speculation that [Zeldis] could have transacted business giving rise to their claims while in New York," Doc. 147 (quoting Doc. 136), and that they had not alleged a genuine issue of jurisdictional fact warranting limited jurisdictional discovery, *Id.*

[44] In the May 31, 2024, pre-motion conference, Zeldis informed the Court that Plaintiffs had recently emailed him regarding a new legal theory whereby they argued that personal jurisdiction over Zeldis was proper because the "correspondence address" on a November 6, 2002, provisional patent application, No. 10/438,213 (the "Provisional Patent Application") was the New York office of the law firm of Pennie & Edmonds, attorneys for Celgene. Plaintiffs reasoned that because Zeldis was the named inventor on the Provisional Patent Application, he was subject to personal jurisdiction in New York based on the attorneys' address. During the conference, Zeldis referenced *Haussmann, Trustee of Konstantin S. Haussmann Trust v. Baumann*, 73 Misc. 3d 1234(A), 157 N.Y.S. 3d 355, 2021 WL 6110467 (Sup. Ct., New York Cnty., Dec. 27, 2021), which held that the New York Supreme Court lacked personal jurisdiction over German defendants as a result of their hiring lawyers located in New York. *Id.* The Court directed supplemental briefing on Plaintiffs' new theory of personal jurisdiction. In its July 9, 2024 Order, the Court held, among other things, that "[t]he fact that Zeldis was listed as the inventor on patents belonging to Celgene—headquartered in New Jersey—and filed in Virginia, by a New York based law firm, without more is simply too tenuous of a connection to New York" to subject him to personal jurisdiction. Doc. 147 at 6.

II. LEGAL STANDARD

A. Rule 12(b)(2) Personal Jurisdiction

A defendant may move to dismiss a plaintiff's claims against it for "lack of personal jurisdiction." Fed. R. Civ. P. 12(b)(2). On a motion to dismiss pursuant to Rule 12(b)(2), the "plaintiff bears the burden of demonstrating personal jurisdiction over a person or entity against whom it seeks to bring suit." *Penguin Group (USA) Inc. v. American Buddha*, 609 F.3d 30, 34 (2d Cir. 2010) (citing *In re Magnetic Audiotape Antitrust Litigation*, 334 F.3d 204, 206 (2d Cir. 2003) (per curiam)); *see also Bank Brussels Lamberts v. Fiddler Gonzalez & Rodriguez*, 171 F.3d 779, 784 (2d Cir. 1999) ("When responding to a Rule 12(b)(2) motion to dismiss for lack of personal jurisdiction, the plaintiff bears the burden of establishing that the court has jurisdiction over the defendant."). To defeat a jurisdiction-testing motion, the plaintiff's burden of proof "varies depending on the procedural posture of the litigation." *Dorchester Financial Securities, Inc. v. Banco BRJ, S.A.*, 722 F.3d 81, 84 (2d Cir. 2013) (quoting *Ball v. Metallurgie Hoboken-Overpelt, S.A.*, 902 F.2d 194, 197 (2d Cir. 1990)). At the pleading stage—and prior to discovery—a plaintiff need only make a *prima facie* showing that jurisdiction exists. *Id.* at 84–85; *see also Eades v. Kennedy, PC Law Offices*, 799 F.3d 161, 167–68 (2d Cir. 2015) ("In order to survive a motion to dismiss for lack of personal jurisdiction, a plaintiff must make a prima facie showing that jurisdiction exists.") (quoting *Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 732 F.3d 161, 167 (2d Cir. 2013)).

If the court considers only pleadings and affidavits, the plaintiff's *prima facie* showing "must include an averment of facts that, if credited by the ultimate trier of fact, would suffice to establish jurisdiction over the defendant." *In re Terrorist Attacks on September 11, 2001*, 714 F.3d 659, 673 (2d Cir. 2013) (quoting *Chloé v. Queen Bee of Beverly Hills, LLC*, 616 F.3d 158, 163 (2d Cir. 2010) (quotation marks and brackets omitted)). Courts may rely on materials outside the pleading in considering a motion to

dismiss for lack of personal jurisdiction. *See DiStefano v. Carozzi North America, Inc.*, 286 F.3d 81, 84 (2d Cir. 2001). "The allegations in the complaint must be taken as true to the extent they are uncontroverted by the defendant's affidavits." *MacDermid, Inc. v. Deiter*, 702 F.3d 725, 727 (2d Cir. 2012) (quoting *Seetransport Wiking Trader Schiffarhtsgesellschaft MBH & Co., Kommanditgesellschaft v. Navimpex Centrala Navala*, 989 F.2d 572, 580 (2d Cir. 1993)).

B. Rule 12(b)(6) Motion to Dismiss

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. et al v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). The plaintiff must allege sufficient facts to show "more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). However, this "flexible 'plausibility standard'" is not a heightened pleading standard, *In re Elevator Antitrust Litigation*, 502 F.3d 47, 50 n.3 (2d Cir. 2007) (quoting *ATSI Communications, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 n.2 (2d Cir. 2007)), and "a complaint . . . does not need detailed factual allegations" to survive a motion to dismiss, *Twombly*, 550 U.S. at 555.

The question on a motion to dismiss "is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Sikhs for Justice v. Nath*, 893 F. Supp. 2d 598, 615 (S.D.N.Y. 2012) (quoting *Villager Pond, Inc. v. Town of Darien*, 56 F.3d 375, 378 (2d Cir. 1995)). "[T]he purpose of Federal Rule of Civil Procedure 12(b)(6) 'is to test, in a streamlined fashion, the formal sufficiency of the plaintiff's statement of a claim for relief without resolving a contest regarding its substantive merits'" or "weigh[ing] the evidence that might be offered to support it." *Halebian v. Berv*, 644 F.3d 122, 130 (2d Cir. 2011) (quoting *Global Network*

Communications, Inc. v. City of New York, 458 F.3d 150, 155 (2d Cir. 2006)). The Court therefore must ordinarily confine itself to the four corners of the complaint and look only to the allegations contained therein. *See id.* When ruling on a motion to dismiss pursuant to Rule 12(b)(6), the Court accepts all factual allegations in the complaint as true and draws all reasonable inferences in the plaintiff's favor. *Nielsen v. Rabin*, 746 F.3d 58, 62 (2d Cir. 2014); *see also Twombly*, 550 U.S. at 556 ("[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable . . . .").

Likewise, "[t]here is no heightened pleading requirement in antitrust cases." *In re Crude Oil Commodity Futures Litigation*, 913 F. Supp. 2d 41, 54 (S.D.N.Y. 2012). However, "a plaintiff must do more than cite relevant antitrust language to state a claim for relief." *Wolf Concept S.A.R.L. v. Eber Bros. Wine & Liquor Corp.*, 736 F. Supp. 2d 661, 667 (W.D.N.Y. 2010) (citing *Todd v. Exxon Corp.*, 275 F.3d 191, 198 (2d Cir. 2001)). "A plaintiff must allege sufficient facts to support a cause of action under the antitrust laws. Conclusory allegations that the defendant violated those laws are insufficient." *Id.* at 667–68 (quoting *Kasada, Inc. v. Access Capital, Inc.*, No. 01-cv-8893 (GBD), 2004 WL 2903776, at *3 (S.D.N.Y. Dec. 14, 2004)). "[A] bare bones statement of conspiracy or of injury under the antitrust laws without any supporting facts permits dismissal." *Heart Disease Research Foundation v. General Motors Corp.*, 463 F.2d 98, 100 (2d Cir. 1972).

III. DISCUSSION

A. Celgene

Section 2 of the Sherman Act, 15 U.S.C. § 2, makes it unlawful for any person to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations . . ." 15 U.S.C. § 2. To state a Section 2 claim of monopolization, a plaintiff must allege "(1) the possession of monopoly power in the relevant market and

(2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litigation*, 383 F. Supp. 3d 187, 219 (S.D.N.Y. 2019) (quoting *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 105 (2d Cir. 2002)). "The latter element requires a plaintiff to establish that 'the defendant has engaged in improper conduct that has or is likely to have the effect of controlling prices or excluding competition.'" *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Takeda Pharmaceutical Co. Ltd.*, 11 F.4th 118, 137 (2d Cir. 2021) (quoting *PepsiCo, Inc.*, 315 F.3d at 108). Plaintiffs must also demonstrate an antitrust injury and damages. *See Cordes & Co. Financial Services., Inc. v. A.G. Edwards & Sons, Inc.*, 502 F.3d 91, 105 (2d Cir. 2007). Celgene asserts that there have been no antitrust violations.

1. Antitrust Scheme

Plaintiffs bring claims pursuant to Section 2 of the Sherman Act, alleging that Celgene effected a scheme which was comprised of (1) fraudulently procuring patents, *i.e.*, *Walker Process* fraud, (2) enforcing those patents in sham litigation against generic manufacturers, and (3) entering into anticompetitive settlement agreements containing unlawful reverse payments, which delayed generic entry into the market for Pomalyst.[45] *See generally* FAC.

At the outset, the parties dispute whether the Court should view the Defendants' alleged conduct as being a cumulative violation of Section 2, or as separate, individual violations, which must each be proven to be anti-competitive. Plaintiffs assert that the Court should view the Defendants' conduct as an overall scheme. Accordingly, they insist that the Court analyze whether this scheme violates the Sherman Act § 2 and

[45] Plaintiffs contend that the FAC does not contain a stand-alone reverse payment claim. Doc. 127 at 28 n. 128. Instead, "the settlement is part of the monopolization scheme. Whether or not the payment is large/unjustified, the settlement's terms and consequences flow from the patent fraud and sham litigation aspects of that scheme and prolongs the consumer harm." *Id.*

analogous state laws not "by dismembering it and viewing its separate parts, but only by looking at it as a whole." Doc. 127 at 13–14 (quoting *Continental Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962) and *In re Electronic Books Antitrust Litigation*, 859 F. Supp. 2d 671, 689 (S.D.N.Y. 2012)). Celgene contends that the Court must analyze each of the claims individually, especially where immunity as an affirmative defense may exist. They assert that Plaintiffs' "settlement and patent claims must each state claims." However, in determining whether multiple anticompetitive acts constitute an antitrust violation, the Court will consider both the alleged individual anticompetitive acts and the overall course of conduct.

The Second Circuit has held that "[t]he proper inquiry is whether, qualitatively, there is a 'synergistic effect.'" *City of Groton v. Connecticut Light & Power Co.*, 662 F.2d 921, 929 (2d Cir. 1981) (citing *Northeastern Telephone Co. v. American Telephone & Telegraph Co.*, 651 F.2d 76 at 95 n.28 (2d Cir. 1981)). "If the evidence underlying each form of alleged anticompetitive conduct is 'utterly lacking,' there can be no synergistic effect." *Valassis Communications, Inc. v. News Corp.*, No. 17-cv-7378 (PKC), 2019 WL 802093, at *9 (S.D.N.Y. Feb. 21, 2019) (citation omitted).

As held in *Valassis*, "in analyzing antitrust claims alleging a variety of anticompetitive conduct, courts must tow the line between two competing considerations. First, the Court must avoid 'tightly compartmentalizing the various factual components' of a plaintiff's claims and 'wiping the slate clean after scrutiny of each.' At the same time, it is unlikely that multiple independently lawful acts can come together to create an unlawful monopoly 'broth' from which antitrust injury can arise." *Valassis*, 2019 WL 802093, at *9 (quoting *City of Groton*, 662 F.2d at 928–29); *see also Pacific Bell Telephone Co. v. Linkline Communications, Inc.*, 555 U.S. 438, 457 (2009); *Eatoni Ergonomics, Inc. v. Research in Motion Corp.*, 486 F. App'x 186, 191 (2d Cir. 2012) (summary order) ("Because these alleged instances of misconduct are not independently anti-competitive, we conclude that they are not cumulatively anti-competitive either.").

Accordingly, in determining whether Celgene's alleged anticompetitive acts constitute an antitrust violation, the Court will consider both the individual acts and the overall course of conduct.

2. Fraud on the PTO & Sham Litigation

a. Noerr-Pennington

The *Noerr-Pennington* doctrine—"a body of case law constituting a limitation on the scope of the Sherman [Antitrust] Act"—originally granted immunity from antitrust liability for conduct that constitutes "petitioning activity" aimed at "persuading the government of a position or expressing views and wishes concerning government decisions." *Covet & Mane, LLC v. Invisible Bead Extensions, LLC*, No. 21-cv-7740 (JPC), 2023 WL 2919554, at *9 (S.D.N.Y. Mar. 23, 2023), report and recommendation adopted, No. 21-cv-7740 (JPC), 2023 WL 6066168 (S.D.N.Y. Sept. 18, 2023) (quoting *Primetime 24 Joint Venture v. National Broadcasting Co., Inc.*, 219 F.3d 92, 99–100 (2d Cir. 2000)); *Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-cv-7343 (HB), 2008 WL 169362, at *1, *3 (S.D.N.Y. Jan. 18, 2008) (citing *Eastern R.R. Presidents Conference v. Noerr Motor Freight Inc.*, 365 U.S. 127, 137–38 (1961) and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965)). "The doctrine was first established in the context of concerted petitions for anti-competitive legislation," but the Supreme Court later extended it to the petitioning of courts and administrative bodies through good faith litigation. *National Broadcasting*, 219 F.3d at 99, 100.

"A patentee who brings an infringement suit may lose *Noerr-Pennington* immunity and be subject to antitrust liability for the anti-competitive effects of that suit if the alleged infringer [or counterclaimant] proves (1) that the asserted patent was obtained through knowing and willful fraud within the meaning of *Walker Process* . . . or (2) that the infringement suit was 'a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.'" *Radiancy, Inc. v. Viatek Consumer Products Group, Inc.*, 138 F. Supp. 3d 303, 324 (S.D.N.Y. 2014)

(quoting *Nobelpharma AB v. Implant Innovations, Inc.,* 141 F.3d 1059, 1068 (Fed. Cir. 1998)).

b. Walker Process Antitrust Standing

Celgene argues that Plaintiffs lack antitrust standing to pursue their monopolization claims under Section 2 of the Sherman Act. "It is a well-established principle that, while the United States is authorized to sue anyone violating the federal antitrust laws, a private plaintiff must demonstrate 'standing.'" *Daniel v. American Board of Emergency Medicine*, 428 F.3d 408, 436 (2d Cir. 2005); *see Paycom Billing Services, Inc. v. Mastercard Int'l, Inc.*, 467 F.3d 283, 290 (2d Cir. 2006) (in addition to demonstrating Article III standing, an antitrust plaintiff must also establish antitrust standing). The Second Circuit has explained that "[a]ntitrust standing is a threshold, pleading-stage inquiry" and that "when a complaint by its terms fails to establish this requirement we must dismiss it as a matter of law." *Gatt Communications, Inc. v. PMC Associates, L.L.C.*, 711 F.3d 68, 75 (2d Cir. 2013) (quoting *NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 450 (6th Cir. 2007) (en banc)). This requirement "prevents private plaintiffs from recovering damages under" the Clayton Act "merely by showing injury causally linked to an illegal presence in the market." *Id.* at 76 (internal quotation marks and alteration omitted).

Private plaintiffs seeking to enforce Section 2 of the Sherman Act must satisfy the standing requirement of Sections 4 and 16 of the Clayton Act, which require an antitrust plaintiff to prove (1) "that it suffered a special kind of antitrust injury" and that (2) "it is a suitable plaintiff to pursue the alleged antitrust violations and thus is an efficient enforcer of the antitrust laws." *Gatt*, 711 F.3d at 76 (citations and internal quotation marks omitted); *see also Xerox Corp. v. Media Sciences Int'l, Inc.*, 511 F. Supp. 2d 372, 380 (S.D.N.Y. 2007). Antitrust injury is "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick*

Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977). Whether a plaintiff is an "efficient enforcer" depends on the following four factors:

> (1) the directness or indirectness of the asserted injury; (2) the existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement; (3) the speculativeness of the alleged injury; and (4) the difficulty of identifying damages and apportioning them among direct and indirect victims so as to avoid duplicative recoveries.

In re DDAVP Direct Purchaser Antitrust Litigation, 585 F.3d 677, 688 (2d Cir. 2009) (quoting *Volvo North America Corp. v. Men's International Professional Tennis Council*, 857 F.2d 55, 66 (2d Cir.1988)). "[T]he weight to be given the various factors will necessarily vary with the circumstances of particular cases." *Emergency Medicine*, 428 F.3d at 443.

First, Celgene, referring to the "first-step rule," asserts that Plaintiffs' injuries are derivative and too remote. Doc. 129 at 11, 12 (quoting *In re American Express Anti-Steering Rules Antitrust Litigation*, 19 F.4th 127, 139–141 (2d Cir. 2021); *see In re American Express*, 19 F.4th at 139 ("In the context of antitrust standing, proximate cause generally follows the first-step rule.")). The first-step rule requires "some direct relation between the injury asserted and the injurious conduct alleged." *Bank of America Corp. v. City of Miami*, 581 U.S. 189, 192 (2017) (quoting *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268 (1992)). "Under the rule, injuries that happen at the first step following the harmful behavior are considered proximately caused by that behavior. Accordingly, "[d]irectness in the antitrust context means close in the chain of causation." *In re American Express*, 19 F.4th at 140 (alteration in original) (quoting *Gatt*, 711 F.3d at 78). Celgene contends that Plaintiffs—customers of pharmacies which initially purchased Pomalyst from Celgene, or entities who reimbursed unspecified customers of such pharmacies—are several steps removed from the PTO and litigation conduct that they challenge.

Next, Celgene contends that alternate "enforcers," such as the generic competitors, are better situated to be efficient enforcers and "challenge the validity of Celgene's patents, such that no alleged antitrust violation would go unremedied." *See, e.g., Farag v. Health Care Service Corp.*, No. 17-cv-2547 (HDL), 2017 WL 2868999, at *4–6 (N.D. Ill. July 5, 2017); *In re K-Dur Antitrust Litigation*, No. 1-cv-1652 (JAG), 2007 WL 5297755, at *18, *19 (D.N.J. Mar. 1, 2007) (emphasis in original) (stating "[i]f this Court were to conclude that *indirect* purchasers had standing to bring *Walker Process* claims, it would turn antitrust policy on its head, and extend antitrust standing to an extraordinary level[.]" and "[A]s compared to competitors and direct purchasers, indirect purchasers have certainly been *less* 'directly harmed[.]'").

Celgene then asserts that Plaintiffs' theory of indirect injury "necessarily involves intermediaries and intervening factors, creating an 'accompanying uncertainty' and 'requir[ing] the court to speculate' about how each intermediary would have behaved had none of the patents issued." Doc. 109 at 23 (alteration in original) (quoting *In re American Express*, 19 F.4th at 142 and *Schwab Short-Term Bond Market Fund v. Lloyds Banking Group PLC*, 22 F.4th 103, 119 (2d Cir. 2021)). Fourth, Celgene asserts that "the requested relief, 'even if in the form of an injunction . . . compounds manageability issues without providing any clear benefit,' particularly where there are better-situated alternative enforcers." Doc. 109 at 23 (citing *In re Aluminum Warehousing Antitrust Litigation*, No. 13-md-2481 (KBF), 2014 WL 4277510, at *23 (S.D.N.Y Aug. 29, 2014)). Finally, Celgene emphasizes that courts consider how their standing analysis, and how expanding that standing, will impact the "incentives for innovation." *Id.* (quoting *In re DDAVP*, 585 F.3d at 691; *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 542 (E.D.N.Y. 2005) (examining whether more expansive standing would "negatively impact the willingness of drug manufacturers to invest in research and development.")).

Plaintiffs, without responding to Celgene's analysis of the factors above, claim that Celgene misstates the law.[46] Doc. 127 at 20.[47] Citing *Walker Process*, they assert that the Supreme Court has rejected arguments trying to limit the type of plaintiff who has standing to bring antitrust claims premised on fraud on the PTO. However, *Walker Process* is inapposite because it involved a competitor, not an indirect purchaser,[48] and Plaintiffs fail to identify any persuasive cases addressing the issue of antitrust standing regarding indirect purchasers.

As Plaintiffs admit, the Second Circuit in *In re DDAVP* "outline[d] a set of factors that courts can consider when determining a party's standing," as described above. Here, the various factors weigh against Plaintiffs being efficient enforcers: Plaintiffs' injuries are derivative and too remote; there are more efficient alternate enforcers, such as the generics; Plaintiffs' theory of indirect injury necessarily involves intermediaries and

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[46] Plaintiffs cite *In re DDAVP Indirect Purchaser Antitrust Litigation*, for the proposition that "the Court need not decide this issue until class certification." Doc. 127 at 20 n.93 (citing 903 F. Supp. 2d 198, 213 (S.D.N.Y. 2012)). However, that case discusses Article III standing, not antitrust standing. *See* Doc. 129 at 12 (citing *In re Digital Music Antitrust Litigation*, 812 F. Supp. 2d 390, 400, 401, 404 (S.D.N.Y. 2011) (holding that, "[i]n addition to Article III standing, an antitrust plaintiff must also establish antitrust standing," while also applying the factors set forth in the Second Circuit's *In re DDAVP* opinion to conclude that plaintiffs failed to establish antitrust standing). Additionally, as stated above, "[a]ntitrust standing is a threshold, pleading-stage inquiry" and that "when a complaint by its terms fails to establish this requirement we must dismiss it as a matter of law." *NicSand*, 507 F.3d at 450.

[47] Plaintiffs cite four cases for the proposition that state law *Walker Process*-type fraud claims do not frustrate the purposes or objectives of federal patent law: *In re DDAVP Indirect Purchaser Antitrust Litigation*, 903 F. Supp. 2d at 217, *Restasis*, 355 F. Supp. 3d at 150, *In re Lipitor Antitrust Litigation*, 336 F. Supp. 3d 395 (D.N.J. 2018), and *Loestrin*, 216 F. Supp. 3d at 357. However, as Celgene asserts, preemption is not at issue here. Doc. 129 at 12.

[48] Plaintiffs cite four cases where the Second Circuit and three other circuit courts considered *Walker Process* claims brought by indirect purchasers for the proposition that the courts did not "throw out" those claims despite being brought by indirect purchasers: *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d, *In re Lipitor Antitrust Litigation*, 868 F.3d 231, 266 (3d Cir. 2017), *United Food and Commercial Workers Unions and Employees Midwest Health Benefits Fund v. Novartis Pharmaceuticals Corp.*, 902 F.3d 1, 8, 9 (1st Cir. 2018), and *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1341 (Fed. Circ. 2008), abrogated by *Actavis*, 570 U.S. at 133. But as Celgene asserts, antitrust standing was not explicitly considered by the courts in those cases. Doc. 129 at 13 (citing *Ontario Public Service Employees Union Pension Trust Fund v. Nortel Networks Corp.*, 369 F.3d 27, 33 (2d Cir. 2004) (rejecting as "unreasonable" plaintiffs' argument that court "implicitly" found standing where opinion never "explicitly addressed the standing requirement" of Rule 10b-5). The Court finds that these cases, having not explicitly addressed the issue of antitrust standing, do not support finding standing here.

intervening factors creating an "accompanying uncertainty" and "requir[ing] the court to speculate" about how each intermediary would have behaved had none of the patents issued; and the requested relief exacerbates manageability issues without providing any clear benefit. *In re American Express*, 19 F.4th at 139, 140; *Schwab*, 22 F.4th at 119; *see also In re Aluminum Warehousing Antitrust Litigation*, 2014 WL 4277510, at *23. Accordingly, Plaintiffs have failed to allege that they are efficient enforcers and that they therefore have antitrust standing to bring *Walker Process* fraud claims against Celgene.

Because the Court holds that Plaintiffs lack antitrust standing to bring *Walker Process* claims, the Court need not reach the parties' arguments based on the merits. *See Arcesium, LLC v. Advent Software, Inc.*, No. 20-cv-04389 (MKV), 2021 WL 1225446, at *10 (S.D.N.Y. Mar. 31, 2021).

c. Fraud on the PTO

Even if Plaintiffs had antitrust standing, they have not made a plausible showing that the six patents were obtained by fraud on the PTO.[49] The FAC states that Celgene, Zeldis, and Insogna repeatedly committed fraud on patent examiners in order to obtain the Pomalyst method of treatment patents, '262, '3939, and '428, and formulation patents, '427, '467, and '5939. ¶¶ 152. Specifically, the FAC alleges that Defendants made false statements and omissions of material fact regarding the pomalidomide method of treatment patents, including:

> (1) the '517 [patent] (falsely stating it does not teach pomalidomide); (2) Davies (2001) (misleading the examiner by suggesting it did not teach pomalidomide to treat multiple myeloma and relapsed/refractory disease); (3) D'Amato (2001) (omitting to disclose it taught pomalidomide to treat multiple myeloma); (4) whether earlier research taught pomalidomide to treat multiple myeloma; (5) whether the prior art taught cyclical dosing; (6) whether it was surprising that the more potent analog pomalidomide

[49] The FAC only alleges that the '262, '3939, and '428 method of treatment patents, and the'427, '467, and '5939 formulation patents were obtained by fraud. ¶¶ 152, 201. However, all nine patents are alleged to have been used in Celgene's sham litigation against the Pomalyst ANDA first filers. ¶¶ 246–251, 273–275, 282–285, 293–296.

> could be used to treat myeloma that had become too resistant to the less potent analog lenalidomide; and (7) whether using pomalidomide to treat refractory and/or relapsed multiple myeloma was surprising.

With respect to the formulation patents, the FAC states that Celgene made false material statements and material omissions by: (1) submitting two false declarations by Anthony Tutino misrepresenting to the examiner that Celgene unexpectedly solved for stability issues; and (2) omitting that Schey (April 2002) taught dosage for pomalidomide. ¶¶ 204, 207.

Plaintiffs assert that the examiner relied on the defendants' false statements and material omissions when issuing the method of treatment and formulation patents and that the patents would not have issued without them. Celgene asserts that Plaintiffs' allegations are either false, not supported by case law, or not sufficiently plead pursuant to Rule 9(b).

A claim for *Walker Process* fraud requires: "(1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation." *In re DDAVP*, 585 F.3d at 692 (quoting *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069–70 (Fed. Cir. 1998)). Such allegations must meet the heightened pleadings standards of Rule 9(b) of the Federal Rules of Civil Procedure, meaning the plaintiff "must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). "A pleading that simply avers the substantive elements of [a claim], without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b)." *Id.* at 1326–27.

i. Method of Treatment

The '262 Patent

Plaintiffs' allegations regarding the '262 patent fail, first, because they do not plausibly plead the materiality of the alleged false representations and material omissions with respect to the final amended application, which resulted in the issuance of the patent. The FAC alleges that on April 9, 2012, the PTO issued a notice of allowance for the '262 patent after multiple rounds of rejections. ¶ 194. To overcome each rejection, the FAC alleges that Celgene made false representations and material omissions in their responses, in addition to submitting amendments, the last of which was submitted on March 15, 2012. ¶¶ 183, 186, 190, 193.[50] However, while the FAC alleges multiple fraudulent representations regarding Celgene's responses to the rejections, it fails to explain how these responses are material to the final amendments, which the patent examiner ultimately approved. Instead, in conclusory fashion, the FAC alleges that the amendment and response was intended to deceive the examiner into withdrawing prior rejections, overlooking or "not appreciat[ing]" previous public disclosures and prior art, and believing that the unexpected results were a lawful basis to allow the claims. ¶ 190. However, this, without more, does not sufficiently allege how the approved final application would not have issued but for the responses to earlier in time rejections to previous applications.

[50] The FAC also alleges that on March 1, 2012, Celgene participated in a telephone call with the patent examiner, and others, where Celgene is alleged to have made additional false misrepresentations and material omissions regarding the cyclical administration of pomalidomide, summarized as follows: "Discussed potential allowability of claims if independent claims are amended to incorporate the limitations of claim 1 of U.S. Pat 7,968,569. Particularly the cyclical administration of the current amounts of the compound for 21 consecutive days followed by 7 consecutive days of rest from administration of the compound in a 28 day cycle in combination with 40 mg of dexamethasone." ¶¶ 191, 192. On March 15, 2012, Celgene submitted a response and statement of interview summary, which amended the claims as contemplated at the March 1, 2021 telephone conference and reiterated that the examiner should withdraw all obviousness objections based on the representations it had made in its December 20, 2011 response. ¶ 193.

Plaintiffs' arguments regarding the '262 patent fail for other reasons. First, although they allege that Celgene made false representations regarding the '517 patent, *i.e.*, alleged prior art that taught a method of treating multiple myeloma with pomalidomide, the examiner's rejection based on the '517 patent was later withdrawn when they admitted incorrectly citing the '517 patent instead of the correct reference, Kyle (2001). ¶¶ 168–174. Accordingly, the examiner did not "justifiably rely" on any misrepresentations based on the '517 patent, which would be required to state a *Walker Process* fraud claim. *In re DDAVP*, 585 F.3d at 692. Next, even though the FAC alleges that Celgene concealed studies that taught pomalidomide to treat multiple myeloma and other cancers, Davies (2001) and D'Amato (2001), the incorporated record reflects that Celgene did in fact disclose the D'Amato (2001). ¶¶ 175, 176. Also, while the FAC alleges that Celgene made false and "misleading statements and material omissions suggesting that the use of one thalidomide compound over another had not been publicly disclosed previously," it does not identify the specific "when, where, and how" of the material misrepresentations or omissions, as required by Rule 9(b). ¶ 188, Doc. 109 at 25 (citing *Exergen*, 575 F.3d at 1327). Additionally, while the FAC alleges that Celgene made false representations regarding prior art teaching of cyclical dosing of pomalidomide with dexamethasone in a March 1, 2012 phone call with the patent examiner, it does not identify the specific statement or representation as required by Rule 9(b). ¶¶ 191–192. Accordingly, Plaintiffs have not plausibly plead *Walker Process* fraud in procuring the '262 patent.

The '428 and '3939 Patents

Plaintiffs' allegation regarding the '428 and '3939 patents are similarly deficient. Plaintiffs allege that Celgene made material misrepresentations regarding the prosecution of the'428 and '3939 patents by "reiterat[ing] many of the same fraudulent misrepresentations and omissions it made to obtain" the '262 patent, and in a declaration submitted to the PTO. ¶ 229. Celgene contends that Dr. Thakurta's "opinion" that the

results were unexpected and surprising are not statements of fact that can support a fraud claim, as a matter of law. Doc. 109 at 39 (quoting *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Novartis Pharmaceutical Corp.*, No. 15-cv-12732 (ADB), 2017 WL 2837002, at *15 (D. Mass. June 30, 2017), *aff'd*, 902 F.3d 1 (1st Cir. 2018)).

First, for the reasons set forth above regarding the '262 patent, Plaintiffs' catch-all claims regarding the "same fraudulent representations and omissions" in the prosecution of the '428 and '3939 patents also fail.

Additionally, in July 2013, Celgene filed a declaration by Dr. Thakurta in response to the patent examiner's initial rejection of the applications—for double patenting of the '262 patent and as obvious over the prior art. ¶ 222. In the declaration, Dr. Thakurta asserts that treating refractory or relapsed multiple myeloma with single-agent pomalidomide would have been "unexpected and surprising at the time." ¶ 226. However, according to Plaintiffs, using pomalidomide to treat refractory or relapsed multiple myeloma was known, and Celgene had already disclosed that pomalidomide was more potent than other thalidomide analogs. ¶¶ 227, 228. By the time of patenting, they contend, it would have been expected that myeloma patients who became resistant to the less potent thalidomide analog, *e.g.*, lenalidomide, could be treated with a more potent thalidomide analog, such as pomalidomide. ¶ 227.

In support of their position, Celgene relies on a case from the District of Massachusetts, *United Food*, 2017 WL 2837002, at *15. In *United Food*, the defendant stated in its patent application to the PTO that certain discovered features of a claimed invention had been "surprising." *United Food*, 2017 WL 2837002, at *15. Like here, the plaintiffs argued that the statement was a misrepresentation intended to deceive the PTO. *Id.* The district court held that the plaintiffs' claim had not been plausibly alleged. *Id.*; *see also United Food*, 902 F.3d at 11. Specifically, the court held that it was "unclear whether such a statement qualifies as a misrepresentation." *United Food*, 902 F.3d at 11.

"The examiner was free to reach [her] own opinion about whether such a discovery was in fact 'surprising' based on the prior art that was available to her before the patent issued." *Id.* (citation omitted). Further, the court held that plaintiffs "have not sufficiently alleged that if [the defendant] had avoided using the word 'surprising,' the patent would not have issued in light of the relevant prior art." *Id.* In affirming the district court, the First Circuit held that the plaintiffs had not shown that the defendants' characterization of the discovered features as "'surprising' was anything more than an assertion of nonobviousness. . . . And the bare assertion that an invention is not obvious—which, of course, is implicit in any patent application—is not in and of itself a material misrepresentation for purposes of *Walker Process*." *Id.* (citing *Akzo N.V. v. United States Trade Commission*, 808 F.2d 1471, 1482 (Fed. Cir. 1986)).

The Court finds *United Food* persuasive. Here too, the Court is not convinced that Dr. Thakurta's characterization of the findings as "unexpected" and "surprising" amount to a misrepresentation before the PTO. The examiner was free to reach their own conclusion based on the relevant prior art.[51] Further, Plaintiffs have not sufficiently alleged that if Dr. Thakurta had avoided using the words "unexpected" or "surprising," the patent would not have issued, considering the relevant prior art. *See id*. Accordingly, Plaintiffs have not plausibly plead *Walker Process* fraud in procuring the '428 and '3939 patents.

ii. Formulation Patents

The '427 Patent

Plaintiffs' allegations regarding the formulation patents fair no better. Regarding the '427 patent, Plaintiffs first allege fraud in Celgene's failure to cite prior art, including Schey (April 2002). ¶¶ 210–218. Additionally, they allege that Celgene made false

[51] In their memorandum in support of the motion to dismiss, Celgene contends that "most of the references Plaintiffs . . . identify [regarding relevant prior art that Dr. Thakurta allegedly omitted] were … cited" to the examiner by Celgene. Doc. 109 at 40; ¶ 227.

representations and omitted material information when they submitted a declaration by Anthony Tutino regarding pomalidomide's "stability." ¶¶ 213–214. Celgene responds that Plaintiffs have not sufficiently plead but-for materiality regarding Schey (April 2002) or plausibly plead fraud regarding the Tutino declaration.

On May 19, 2010, Celgene filed the patent application that would lead to the '427 patent. ¶ 207. The initial patent application "claimed an oral dosage form of a given weight … comprised of pomalidomide and a pharmaceutically accepted carrier or excipient." *Id*. In the initial rejection, on April 24, 2012, the examiner noted that "[i]t would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to have made oral dosage forms comprising pomalidomide and excipients . . . with a reasonable expectation of success because Zeldis *et al*. taught such oral dosage forms." ¶ 208. The examiner viewed the claimed amounts of active and excipient ingredients as ranges, instead of specific amounts. ¶ 209. In response, Celgene, through Insogna, argued that "although Zeldis may generally disclose a laundry list of [compositions] containing pomalidomide in combination with a broad range of possible excipients that may be used in such compositions, there is no disclosure in Zeldis that would have prompted one skilled in the art to prepare a composition having pomalidomide at the specified amounts, along with the particular binders and fillers" as claimed. ¶ 210. Plaintiffs assert that in Celgene's response, they concealed the prior art, including Schey (April 2002), which taught pomalidomide dosage amounts up to a maximum tolerated dosage of 5 mg per day.

However, as Celgene points out—and again, Plaintiffs do not directly contest—the FAC does not allege the materiality of Schey (April 2002) to the issued patent. Doc. 109 at 41. As Plaintiffs acknowledge, on November 15, 2012, the examiner would reject the amended application, "despite Celgene's [responses]."[52] Additionally, the FAC does

[52] Celgene amended the application on August 16, 2012, in addition to providing a response to the examiner's objections and rejections on April 24, 2012. ¶¶ 208, 210.

not connect Celgene's response, or omission of Schey (April 2002), to an earlier in time rejection—even if fraudulent—to the final, issued patent claims. *Id*. This is insufficient under Rule 9(b). Under Rule 9(b), allegations of fraud are deficient where, as here, "the pleading fails to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found—*i.e*., the "what" and "where" of the material omissions." *Exergen,* 575 F.3d at 1329.

On June 17, 2023, after the examiner's second rejection, Celgene and Insogna filed the Tutino declaration stating that while many pomalidomide-excipient combinations he tested posed stability issues over time, the claimed invention did not, a result he found "unexpected." ¶ 213. Plaintiffs assert that the declaration was fraudulent because it (1) relied on "false," undated data and (2) misled the examiner about known art regarding pomalidomide's "stability." ¶¶ 213–214.

As Celgene asserts, Plaintiffs have not plausibly plead—or plead at all—why the data being undated is material to the patents' issuing by the PTO. Doc. 109 at 14, 42 (citing *See Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1307 (Fed. Cir. 2011) ("[E]vidence of unexpected results may be used to rebut a case of *prima facie* obviousness even if that evidence was obtained after the patent's filing or issue date."). Additionally, Plaintiffs do not assert the "what" or "how" of the alleged false data in the Tutino declaration. Doc. 109 at 42; *Exergen*, 575 F.3d at 1328. Accordingly, Plaintiffs have not plausibly alleged fraud in Celgene's procurement of the '427 patent.

The '467 and '5939 Patents

The same is true for the '467 and '5939 patents. Like with Dr. Thakurta's declaration during the prosecution of the '428 and '3939 patents, Plaintiffs allege that Celgene "lied and omitted material information" to the PTO when they submitted two declarations by Tutino, "falsely stating" that the stability results were "surprising" and

"unexpected." ¶¶ 212–214, 241, 243. However, as held above, the Court is not convinced that Tutino's declarations characterizing the results as "unexpected" and "surprising" amount to a misrepresentation before the PTO. The examiner was free to reach his own opinion based on the relevant prior art. *See United Food,* 902 F.3d at 11 (citing *Akzo N.V.*, 808 F.2d 1471, 1482 (Fed. Cir. 1986)). Again, Plaintiffs have also not sufficiently alleged that if Tutino had avoided using the words "unexpected" or 'surprising," the patent would not have issued considering the relevant prior art. *See* id. In fact, when issuing the '5939 patent, subject to a terminal disclaimer, the examiner expressly declined to agree with Celgene's argument of unexpected results in evaluating the patent. ¶¶ 270, 271.

Accordingly, Plaintiffs have not plausibly plead *Walker Process* fraud in procuring the '428 and '3939 patents. Furthermore, having failed to plausibly plead fraud as to any of the six patents allegedly obtained by fraud, Celgene's motion to dismiss the FAC is GRANTED as to Plaintiffs' *Walker Process* fraud claims.

d. Sham Litigation

Plaintiffs allege that when Celgene filed its infringement actions, between May 2017 and March 2020, they knew that they had no realistic chance of succeeding in the patent infringement litigation, yet they pursued the lawsuits to prevent or delay the ANDA first filers' entry into the Pomalyst generic market. ¶ 3. Celgene argues that Plaintiffs have failed to establish that the nine lawsuits were objectively baseless.

"Under the *Noerr–Pennington* doctrine, litigation as well as concerted efforts incident to litigation may not serve as a basis for an antitrust claim." *Viva Optique, Inc. v. Contour Optik, Inc.*, No. 03-cv-8948 (LTS) (AJP), 2007 WL 4302729, at *2 (S.D.N.Y. 2007). "However, under the 'sham exception' to the doctrine, *Noerr–Pennington's* antitrust immunity does not apply where litigation or other petitioning activity 'is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the

business relationships of a competitor.'" *Id.* (citation omitted). In order to bring a sham litigation claim, a plaintiff must plausibly plead that the litigation was:

1. 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits'; and
2. subjectively motivated by a desire to 'interfere *directly* with the business relationships of a competitor,' through the use of the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon.'

In re Solodyn (Minocycline Hydrochloride) Antitrust Litigation, No. 14-md-02503 (DJC), 2015 WL 5458570, at *11 (D. Mass. Sept. 16, 2015) (quoting *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries*, 508 U.S. 49, 60–61 (1993)). For the purposes of this motion, the parties do no dispute that the second prong is met.

Patents issued by the PTO have a strong presumption of validity in infringement proceedings. *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999) (citing 35 U.S.C. § 282 (1994)); *see also Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353, 381–82 (S.D.N.Y. 2007); *Carotek, Inc. v. Kobayashi Ventures, LLC*, 875 F. Supp. 2d 313, 326 (S.D.N.Y. 2012). However, where a patent infringement action is brought "'with knowledge the patent is invalid or not infringed, and the litigation is conducted for anti-competitive purposes' [the case] is a 'sham' litigation." *Radiancy, Inc. v. Viatek Consumer Products Group, Inc.*, 138 F. Supp. 3d 303, 326 (S.D.N.Y. 2014), as amended (Apr. 1, 2014) (alteration in original) (quoting *Teva Pharmaceutical Industries, Ltd. v. Apotex*, Inc., No. 7-cv-5514 (GEB) (JJH), 2008 WL 3413862, at *5 (D.N.J. Aug. 8, 2008)).

The sham exception should be construed narrowly so as to avoid intrusion upon, or a chilling of, one's right to petition under the First Amendment. *See Professional Real Estate*, 508 U.S. at 56; *see also BE&K Construction Co. v. N.L.R.B.*, 536 U.S. 516, 532 (2002). The burden of proving the exception rests with the party attempting to invoke it. *See Professional Real Estate*, 508 U.S. at 60; *see also Hospital Building Co. v. Trustees of Rex Hospital*, 791 F.2d 288, 292–93 (4th Cir. 1986) (finding no error in the

lower court's instruction that the burden of proving the sham exception is properly on the party attempting to invoke it) (citing *California Motor Transportation Co. v. Trucking Unlimited*, 404 U.S. 508, 518 (1972) (Stewart, J., concurring)); *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015) ("*Professional Real Estate*'s exacting two-step test properly places a heavy thumb on the scale in favor of the defendant.").

"While various courts outside of this Circuit have generally regarded the applicability of the sham exception as a question of fact for the jury, a court may decide this issue as a matter of law where 'there is no dispute over the predicate facts underlying the legal proceeding.'" *In re Elysium Health-Chromadex Litigation*, 354 F. Supp. 3d 330, 336 (S.D.N.Y. 2019), as amended (Feb. 7, 2019) (internal citation omitted) (quoting *Professional Real Estate*, 508 U.S. at 62).

For the reasons given below, the Court cannot conclude that Celgene's infringement actions against the Pomalyst ANDA first filers were objectionably baseless, such that "no reasonable litigant could realistically expect success on the merits." *Professional Real Estate*, 508 U.S. at 60.

First, Celgene asserts that because the lawsuits were ultimately resolved with settlements, they had outcomes favorable for Celgene and therefore cannot be a sham. Specifically, they contend that "every suit challenged here reached a settlement and consent judgment that preserved the viability and validity of Celgene's patents and allowed Celgene to retain a significant portion of its patent rights[.]" This is particularly true where there are no unlawful provisions in the settlements, as Celgene argues is the true here. Plaintiffs contend that a successful settlement does not immunize Celgene against a finding that the lawsuits were a sham. They assert that there are numerous cases involving sham litigation based on generic delay that have survived a motion to dismiss, particularly where the settlements were challenged as being anticompetitive. In contrast,

they allege that there are no cases definitively precluding a finding of sham litigation based solely on there being a favorable settlement.

While generally "a winning lawsuit [or a favorable settlement] is 'a reasonable effort at petitioning for redress and therefore not a sham,'" a settlement does not "*ipso facto* constitute a determination of the 'objective reasonableness' of the lawsuit, especially in a case where the plaintiff claims the judgement [or settlement] in the prior action was obtained through deceit." *T.F.T.F. Capital Corp. v. Marcus Dairy, Inc.*, 312 F.3d 90, 94 (2d Cir. 2002). However, as further discussed below, Plaintiffs have not plausibly alleged that the settlements were fraudulent, *i.e.*, that they contained unlawful reverse payments.

The court in *In re Elysium,* held that courts, "both in this Circuit and in others," have concluded that "settlement of a purportedly objectively baseless lawsuit constitutes a favorable outcome within the meaning of *Noerr-Pennington* and therefore insulates the activity from application of the sham exception." 354 F. Supp. 3d at 338. In *In re Elysium*, the defendant CMDX filed a petition that sought to remove a product from the market, because it contained a certain "deleterious" substance. *Id*. at 337. After the filing of the petition, *i.e.*, the alleged "sham" lawsuit, Elysium removed the deleterious substance. *Id.* at 338. In determining the motion for summary judgement, the Court held, in part, that because CMDX's petition was successful, the petition was therefore not a sham. *Id.* at 337–40. Here, Plaintiffs have not plausibly alleged that the settlements were procured by fraud. Accordingly, the Court finds that the positive resolution of the lawsuits suggests that Celgene's lawsuits against the Pomalyst ANDA first filers were "a reasonable effort at petitioning for redress and therefore not a sham." *T.F.T.F. Capital*, 312 F.3d at 94.

Next, Celgene asserts "where, as here, the accused infringer files an ANDA borrowing the patentee's data but challenging its patents with a so-called Paragraph IV certification, the patentee necessarily has "an objectively reasonable basis to sue."[53]

While it's true that the submission of an ANDA is, by statutory definition, an infringing act, an infringement suit filed in response to an ANDA with a paragraph IV certification "could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification." *Blue Cross & Blue Shield of Vermont v. Teva Pharmaceutical Industries, Ltd.*, 712 F. Supp. 3d 499, 526 (D. Vt. 2024) (quoting *FTC v. AbbVie Inc.*, 976 F.3d 327, 361 (3d Cir. 2020)). Here, the bulk of Plaintiffs' assertions regarding noninfringement or invalidity rests on Celgene's alleged fraud on the PTO in procuring the six method of treatment and formulation patents. ¶¶ 246–296. However, as discussed, Plaintiffs have not plausibly alleged fraud as to these patents. Without sufficiently alleging fraud, no plausible allegations remain suggesting how Celgene's lawsuits regarding these patents would be objectively baseless.[54]

Additionally, Plaintiffs' allegations regarding the three polymorph patents are also flawed. First, instead of pleading that the polymorph patents were obtained through fraud on the PTO, Plaintiffs assert that Celgene had no colorable basis for asserting the patents because they were "applied for *after* the generic companies had already served paragraph IV notices." ¶ 320. On December 20, 2017, months after the Pomalyst generics filed their ANDAs and served paragraph IV notices, Celgene filed the patent applications that

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[53] Plaintiffs do not respond to this argument.

[54] Plaintiffs also contend that the June 2020 *Markman* decision eliminated any "continued pretense" that the method of treatment patents were valid. Doc. 127 at 25. However, as Celgene asserts, this intermediate court ruling cannot plausibly allege sham litigation, where Celgene was not "'require[d] … to divine the outcome … before filing,' a point 'especially true in the Hatch-Waxman context.'" Doc. 129 at 18 (citing *In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class*, 868 F.3d 132, 151 n.22 (3d Cir. 2017).

would lead to the polymorph patents. ¶¶ 282–285, 320. On October 9, 2018, the PTO allowed the '647, '648, and '649 patents to issue; and on February 14, 2019, Celgene began suing Pomalyst ANDA first filers for infringement of those patents. ¶ 282. According to Plaintiffs, the fact that the paragraph IV certifications were served on Celgene before they applied for the polymorph patents belies their assertion that the patents were novel over the prior art, and thus valid and infringed by the Pomalyst ANDA first filers.

However, Plaintiffs provide no plausible allegation as to why a patent applied for after a generic has filed a paragraph IV certification cannot still be valid over the prior art, which Celgene asserts "is not uncommon." Doc. 109 at 49 (citing *e.g.*, *Research Foundation of State University of New York v. Mylan Pharmaceuticals, Inc.*, Nos. 9-cv-184 (LPS), 10-cv-892 (LPS), 2012 WL 1901267, at *5 (D. Del. May 25, 2012) (granting injunction in a Hatch-Waxman case on a patent that issued over a year after the generic's ANDA was filed)).

Second, Plaintiffs assert that "even if the patents were valid, no reasonable pharmaceutical company could expect to prevail on claims that all three . . . were infringed" by each Pomalyst ANDA product. However, Celgene correctly argues that it is not unusual to assert multiple polymorph patents, *see, e.g.*, *Lundbeck v. Apotex Inc.*, No. 18-cv-88 (LPS), 2020 WL 3507795, at *1 (D. Del. June 26, 2020) (four polymorph patents), and Plaintiffs provide no plausible allegations as to why the Court should find differently here.[55]

Accordingly, Plaintiffs cannot show that no reasonable person could disagree with the assertions of noninfringement or invalidity in the certifications of the Pomalyst ANDA first filers. *See AstraZeneca AB v. Mylan Laboratories, Inc.*, No. 00-cv-6749

[55] In the FAC, Plaintiffs allege that the formulation and polymorph patents, even if valid, were not infringed because generics "could" have "designed around" them. ¶¶ 218, 245, 251, 256, 272, 274, 458. However, allegations that Celgene's claims were weak are insufficient, alone, to plead sham litigation. *See AbbVie*, 42 F.4th at 712-13 (not an antitrust violation to assert allegedly "weak" patents).

(BSJ), 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010), *aff'd sub nom*. *In re Omeprazole Patent Litigation*, 412 F. App'x 297 (Fed. Cir. 2011). As such, the Court finds that Celgene is entitled to *Noerr–Pennington* immunity from antitrust liability arising from its patent infringement actions against the Pomalyst ANDA first filers because the suits were not a sham.

ii. Serial Petitioning

In their opposition to the instant motion, Plaintiffs contend that the Court should apply the lesser standard used for serial petitioning, *i.e.*, "serial petitions filed with the subjective intent to interfere with competition can be a sham even if individual petitions are *not* objectively baseless." Doc. 127 at 22, 23 (citing *California Motor Transportation Co.*, 404 U.S. at 511, 113; *Otter Tail Power Co. v. U.S.*, 410 U.S. 366, 380 (1973); *Primetime 24*, 219 F.3d 92. In response, Celgene contends that the Court "should follow the overwhelming weight of authority," holding that the serial petitioning exception "is particularly inapt" in the Hatch-Waxman context. *See In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class*, 868 F.3d 132, 157–58 (3d Cir. 2017) (citing 21 U.S.C. § 355(j)(5)(B)(iii)) ("The Act incentivizes brand-name drug manufacturers to promptly file patent infringement suits by rewarding them with a stay of up to 30 months if they do so. We are not inclined to penalize a brand-name manufacturer whose 'litigiousness was a product of the Hatch-Waxman.'"), *judgment entered sub nom. In re Wellbutrin XL Antitrust Litigation*, No. 15-cv-2875 (KAJ) (TIV) (RLN), 2017 WL 3529114 (3d Cir. Aug. 9, 2017).

In serial, or automatic petitioning cases, "[i]t is immaterial that some of the claims might, as a matter of chance, have merit. The relevant issue is whether the legal challenges are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival." *AstraZeneca AB*, 2010 WL 2079722, at *3 (alteration in original) (quoting *Primetime 24*, 219 F.3d at 101). Here, the Court has already held that Plaintiffs have not sufficiently plead allegations of fraud

on the PTO. Without these allegations, the FAC cannot sufficiently allege that the Celgene's Hatch-Waxman lawsuits were "brought without regard to the merits."

3. Reverse Payment Claims

The Parties dispute whether the terms of the settlement agreements between Celgene and the generic manufacturers are subject to antitrust scrutiny. Plaintiffs allege in counts I, IV, and V that Celgene unlawfully monopolized the market for Pomalyst by settling the lawsuits with the nine generics through agreements that delayed generic competition in that market. ¶¶ 1, 4, 247–282, 325. In exchange for delayed generic entry, according to Plaintiffs, those settlements contained reverse payments, including Celgene's "protect[ion]" of unlawful monopoly profits with those same generics in the market for Revlimid, "protection of the risks that [the ANDA first filers] had forfeited [their] 180-day statutor[ily] provided exclusivity," and "simultaneously timed" delayed entry dates for the ANDA first filers. ¶¶ 1, 4, 313–336, 346–352, 359, 353–363. Although Plaintiffs sue under both federal antitrust law and a variety of state statutes, the parties rely on the legal standards set forth in *Actavis* and its progeny for evaluating a reverse payment settlement, and the Court will do the same.

In *Actavis*, the Supreme Court held that reverse payments "can sometimes unreasonably diminish competition in violation of the antitrust laws," 570 U.S. at 141, "reverse" meaning that "the settlement required the patentee plaintiff to pay the alleged infringer rather than the other way around[.]" *In re Bystolic Antitrust Litigation*, 657 F. Supp. 3d 337, 349 (S.D.N.Y. 2023), *aff'd sub nom. Watson Laboratories, Inc*. 101 F.4th 223 (2d Cir. 2024). In *Actavis*, the Supreme Court held that there were four principal considerations regarding reverse payments. First, it noted that "reverse payments can be anticompetitive because they allow a brand-name company to split its monopoly profits with a generic company willing to delay market entry." *AbbVie Inc.*, 976 F.3d at 352 (citing *Actavis*, 570 U.S. at 153–56). Second, it recognized that the anticompetitive consequences of reverse payments will "at least sometimes prove unjustified." *Actavis*,

570 U.S. at 138.[56] Third and fourth, it explained that "the 'size of [an] unexplained reverse payment can provide a workable surrogate for a patent's weakness' and a patentee's market power, 'all without forcing a court to conduct a detailed exploration of the patent itself.'" *AbbVie Inc.*, 976 F.3d at 352 (citing *Actavis*, 570 U.S. at 157–58) (alteration in original). Fifth, the Supreme Court made clear that "subjecting reverse payments to antitrust review does not violate the general legal policy in favor of settlements," because a patentee and purported infringer may still lawfully settle their suit by other means. *Id.* (citation omitted); *Actavis*, 570 U.S. at 158. It observed, for instance, that they may settle by "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Actavis*, 570 U.S. at 158. Ultimately, the Court concluded, "a reverse payment, where *large and unjustified*," can violate the antitrust laws. *Id.* at 158–60 (emphasis added); *see also Revlimid*, 2024 WL 2861865, at *51–52.

Pursuant to *Actavis* therefore, to trigger antitrust concern, the settlement terms at issue must be (1) a "payment" that is (2) made in "reverse," and is (3) "large," and (4) "unexplained." *See id.* at 157–58. Reverse payments are not presumptively unlawful, however, because the "existence and degree of any anticompetitive consequence" may vary depending on the particular settlement and the relevant industry. *Id.* at 159. Plaintiffs must therefore prove their case under the rule of reason analysis applied to other types of antitrust claims. *Id.* In this Circuit, the rule of reason analysis proceeds in three steps:

> First, the plaintiff bears the initial burden of showing that the defendant's conduct had an actual adverse effect on competition as a whole in the relevant market. If plaintiff satisfies this burden, the burden then shifts to [the] defendant to offer evidence that its conduct had pro-competitive effects. If [the] defendant is able to

[56] On the one hand, a defendant might show that "traditional settlement considerations, such as avoided litigation costs or fair value for services" justified the reverse payment. *Actavis*, 570 U.S. at 156. Conversely, antitrust scrutiny could reveal "a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement," in which case the payment is not justified. *Id.*

> offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives.

Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 104 (2d Cir. 2010), *as corrected* (June 17, 2010) (internal citations and quotation marks omitted).

The Court begins its inquiry by assessing whether Plaintiffs have plausibly pleaded a reverse payment with anticompetitive effect. For the purposes of this motion, the parties do not dispute that the alleged payments are "reverse." Instead, Celgene contends that Plaintiffs have failed to plausibly allege that the challenged Pomalyst settlements "protected" profits in the market for Revlimid or how any such protection "amounted to a 'payment.'" Further, Celgene argues that the challenged settlement provisions—containing early entry licenses to the generic manufacturers and 'simultaneously timed' early entry dates (*i.e.*, 'acceleration clauses')—do not constitute unlawful reverse payments. Finally, Celgene contends that even if these may be characterized as "payments," Plaintiffs have failed to plausibly allege that they were "large" or "unexplained" as required by Actavis.[57]

a. Protections in Revlimid Settlement

Plaintiffs allege that Celgene made a reverse payment to the settling Pomalyst ANDA first filers when they agreed to delay entry in the generic Pomalyst market in exchange for "protect[ion of] unlawful-market allocation agreements reached by the same [generic manufacturers]" in the market for Revlimid. ¶¶ 4, 313–336, 346–352, 353–363. Specifically, Plaintiffs allege that the ANDA first filers' agreement to delay generic entry in the Pomalyst market was in exchange for a reverse payment of "protected" monopoly profits—via volume-limited, royalty-free licenses and MFE clauses—in the market for generic Revlimid. ¶¶ 325, 327, 349, 360; 172 at 22. Celgene asserts that Plaintiffs have

[57] In the FAC, Plaintiffs contend that the confidential nature of the settlements is another aspect of their monopolization scheme. ¶¶ 330–332, 351, 352, 363. However, as Celgene points out, Plaintiffs fail to respond to its arguments refuting Plaintiffs' confidential nature allegations in their memorandum in response to the motion, and thus concede them. Doc. 129 fn. 2.

failed to plausibly allege how the Pomalyst settlements "protect" the Revlimid settlements. Additionally, they contend that Plaintiffs cannot "bootstrap" the existence of claims in an unrelated legal proceeding in the District of New Jersey as a basis to proceed here.

To support their claims, Plaintiffs must first plausibly establish that the Pomalyst and Revlimid settlement agreements are related. The Court concludes that they are not. "A settlement agreement may be very simple or tremendously complex, and it may involve all manner of consideration; and if, when viewed holistically, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement." *In re Aggrenox Antitrust Litigation*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015). "Where a plaintiff has plausibly pleaded that several agreements are connected, the Court must accept those allegations as true on a motion to dismiss." *In re Bystolic Antitrust Litigation*, 2022 WL 594534, at *17 (citing *AbbVie Inc*, 976 F.3d at 358).

Plaintiffs cite to *Impax Labs* for the contention that the Court can assess whether the circumstances of a side deal "suggest[s] that the agreement may have been a means of masking value transferred in exchange for eliminating the risk of competition." Doc. 127 at 29 (citing *In the Matter of Impax Laboratories, Inc.*, No. 9373, 2019 WL 1552939, at *21 (F.T.C. Mar. 28, 2019)). But *Impax Labs* does not help them in demonstrating that the Pomalyst and Revlimid settlements are related. In *Impax Labs,* the Federal Trade Commission considered whether an initial agreement and a purported side agreement were related. *Id.* The Commission concluded that they were, because the side agreement had been negotiated and executed simultaneously with the initial agreement while also being incorporated into it. *Id.* Not so here. Despite the fact that the FAC alleges that each of the nine agreements between Celgene and the Pomalyst ANDA first filers were "simultaneously reached" with "identical timing" to agreements reached by those same generic companies and Celgene in the market for Revlimid, only one pair, the Aurobindo

agreement with Celgene regarding Revlimid and the Aurobindo agreement with Celgene regarding Pomalyst, was actually alleged to have been reached on the same day. ¶¶ 360, 366. Otherwise, only three of the other eight pairs have execution and filing dates within proximity of one another, with each being more than a month apart.[58] ¶¶ 4, 316, 329, 356, 362, 367. Furthermore, as Celgene asserts, the FAC identified no reference to or provision within any of the Pomalyst settlements mentioning the Revlimid agreements—or Revlimid at all—nor any other plausible reason to believe that the Revlimid agreements were incorporated within them, or the reverse.[59]

Plaintiffs next cite to *AbbVie*, where the Third Circuit, reversing the district court, held that two settlement agreements based on products in separate markets could be linked. *AbbVie Inc.*, 976 F.3d at 358. In *AbbVie*, the FTC brought an action for unlawful restraint of trade against the Abbott-owned company AbbVie. *Id.* at 388. AbbVie had settled with generic Teva regarding patent litigation over the drug AndroGel and a supply agreement over TriCor, a pharmaceutical drug in a separate market. *Id.* at 344. While the district court dismissed the FTC's reverse payment theory, the Third Circuit reversed, holding that separate agreements to delay entry in the market for one product in exchange for value transferred in the market for a different product could constitute an unlawful reverse payment. *Id*. at 358. In doing so, the Third Circuit held that the FTC had

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[58] The FAC includes a chart depicting the dates when five generics—Alvogen, Apotex, Hetero, Mylan, and Dr. Reddy's—filed Pomalyst consent Judgements and when the Revlimid settlements were disclosed to the public. *Id.* For the ANDA first filers Alvogen, Apotex, and Hetero, the filing and disclosed settlement dates are just over a month apart. *Id.* For Mylan, the estimated settlement date of Pomalyst and the disclosed settlement date of Revlimid are approximately four months apart. *Id.* For Dr. Reddy's, the filing and disclosed settlement dates are more than a year apart. *Id.* The FAC also alleges that Natco, and their then commercial partner, Teva, reached a settlement agreement with Celgene regarding Revlimid "in early 2015." ¶¶ 314. However, Natco, and then commercial partner, Breckenridge, did not reach a settlement agreement with Celgene regarding Pomalyst until "late October or early November 2020," and Teva did not reach a settlement agreement with Celgene for Pomalyst until March 2021. ¶¶ 325, 346.

[59] Plaintiffs' reference to *In re Loestrin 24 Fe Antitrust Litigation*, 261 F. Supp. 3d 307, 337 (D.R.I. 2017) for the proposition that the Court can read together each settling generics' Polymast and Revlimid agreements with Celgene also fails. Doc. 127 at 29. Unlike the instant case, *Loestrin* contemplated co-promotional arrangements regarding separate drugs expressed in a *single agreement* and executed on the same day. *In re Loestrin*, 261 F. Supp. at 337.

plausibly alleged that the AndroGel and TriCor agreements were linked because the two agreements had been settled on the same day, along with other "unusual" aspects of the supply agreement which connected it to the initial settlement agreement. *Id.* at 357. However, as discussed above, Plaintiffs have not plausibly alleged a connection between the Pomalyst and Revlimid agreements for any of the eight settling Pomalyst ANDA first filers.[60]

b. 180-Day Exclusivity Period

Plaintiffs next allege that Celgene provided the Pomalyst ANDA first filers "protection of the risks that [they] had forfeited [their] 180-day statutor[ily] provided exclusivity." ¶¶ 323, 359. That is, as first filers of the Pomalyst ANDAs, Natco/Breckinridge and Aurobindo, among others, were entitled to a 180-day period of exclusivity from the first commercial marketing of the generic, during which no generic manufacturers other than the Pomalyst ANDA first filers could enter the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii), (iv). A first filer, however, *can* forfeit this exclusivity period if it fails to obtain tentative FDA approval of its ANDA within 30 months of filing. ¶ 34. According to Plaintiffs, the exclusivity agreement ensured Natco/Breckinridge and Aurobindo that they could enter the market earlier than they otherwise would be allowed under the terms of the settlement agreement in the event the patents were invalidated and retain their 180-day period of exclusivity, which was extremely valuable.

Celgene contends that Plaintiffs' 'protection of risk' allegation is no more than speculation and therefore not a plausible pleading of a "reverse payment." According to Celgene, what Plaintiffs term a "contractual exclusivity" is a provision of the settlement

[60] Plaintiffs' other referenced cases are no more persuasive. As Celgene asserts, the other cases that Plaintiffs cite "in support of their … theory are wholly distinguishable … [and] involve[] … allegations about: settlements specifically designed to allow for an 'anticompetitive product-hop' between different drugs, *Sergeants Benevolent Association Health & Welfare Fund v. Actavis*, 2016 WL 4992690, at *15 (S.D.N.Y. Sept. 13, 2016) ("*Namenda*"); co-promotional arrangements as to separate drugs expressed in a single agreement, *In re Loestrin*, 261 F. Supp. 3d at 334-37; and an alleged no authorized generic ("non-AG") agreement, *In re Xyrem Antitrust Litig.*, 555 F. Supp. 3d 829, 852 (N.D. Cal. 2021)." Doc. 129 at 6. None of these issues are pleaded here.

that lawfully "accelerates earlier in time the patent license for a generic to launch its product." Additionally, Celgene asserts that the FDA commonly defers decisions on forfeiture and therefore the risk faced by Natco/Breckinridge and Aurobindo is a risk faced by all first filers. Furthermore, even if Natco/Breckinridge and Aurobindo faced a risk of forfeiture, had any one of the other first filers preserved its exclusivity, all of the first filers would be allowed to participate in that exclusivity.

In support of their argument, Plaintiffs cite to *Staley v. Gilead Sciences Inc.*, 446 F. Supp. 3d 578 (N.D. Cal. 2020). In *Gilead*, the court held that an MFEP clause in the brand-generic settlement agreement could "resurrect[]" the already forfeited exclusivity of the ANDA first filer and be "a significant deterrent to second filers." 446 F. Supp. 3d at 612. As Celgene notes, however, in *Gilead*, the plaintiffs asserted that the ANDA first filer had already forfeited the 180-day ANDA exclusivity at the time of the patent settlement, and thus the MFEP clause essentially "resurrect[ed]" it. Not so here. Here, Plaintiffs only refer to a potential risk that Natco/Breckinridge and Aurobindo *could* forfeit their exclusivity. ¶¶323, 359. As even Plaintiffs admit, and as discussed above, "the FDA will commonly defer a decision on forfeiture until it becomes necessary to decide the issue" and "failure to obtain tentative approval within the specified time period does not always result in forfeiture." ¶ 34; Doc. 109 at 11 (citing *Hi-Tech Pharmacal Co. v. Federal Drug Administration*, 587 F. Supp. 2d 1, 5 (D.D.C. 2008) (explaining that the FDA's "general practice is to decide issues of exclusivity and forfeiture only when an ANDA is ready for final approval")).

Furthermore, even if Natco/Breckinridge and Aurobindo were unable to preserve their 180-day exclusivity within the 30-month window, any preservation on the part of the other Pomalyst ANDA first filers would allow Natco/Breckinridge and Aurobindo to retain their exclusivity. Docs. 109 at 14, 15; 129 at 8; *see* FDA, Guidance for Industry: 180-Day Exclusivity 26 (Jan. 2017); *see also Actavis*, 570 U.S. at 174–75 (Roberts, C.J., dissenting) (citing FDA, Guidance for Industry: 180-Day Exclusivity When Multiple

ANDAs Are Submitted on the Same Day 4 (July 2003)); *Sergeants Benevolent Association Health & Welfare Fund v. Actavis, PLC*, No. 15-cv-6549 (CM), 2018 WL 7197233, at *6 (S.D.N.Y. Dec. 26, 2018) ("[M]ultiple filers may share the exclusivity period if they file on the same day.").[61] Accordingly, Plaintiffs have proffered no plausible reason to suggest that Natco/Breckinridge, Aurobindo, or the other Pomalyst ANDA first filers who settled were at "risk" or how that risk would constitute a reverse payment from Celgene.

c. Simultaneously Timed Early Entry Dates

The FAC next alleges that the separate settlement agreements between Celgene and Natco/Breckinridge, Aurobindo, and Teva contained identical, "simultaneously timed" delayed entry dates for the ANDA first filers. ¶¶ 4, 316, 329, 356, 362. Further, the FAC alleges that these delayed entry dates ensured that the generics in the Revlimid settlements would continue to protect the profit-sharing agreement, *i.e.*, the profits generated from the Revlimid settlement agreement, and not compete for entry in the Pomalyst market before the other generics. ¶¶ 4, 316, 329, 356, 362. Plaintiffs further assert that these provisions deter "other generics from continuing to challenge Celgene's patents and provides assurance to the generics that they will receive the most favorable entry dates[.]" ¶ 326.

Celgene contends that *Actos* rejected the assertion that provisions in the settlement agreements that contain an acceleration clause could constitute a reverse payment. Docs. 109 at 16, 17; 129 at 8, 9; *In re Actos End Payor Antitrust Litigation*, No. 13-cv-9244 (RA), 2015 WL 5610752, at *15 (S.D.N.Y. Sept. 22, 2015), *aff'd in part, vacated in part*, 848 F.3d 89 (2d Cir. 2017). According to Celgene, even Plaintiffs concede that other courts have found that an acceleration clause cannot "*on its own*"

[61] According to the FAC, on December 6, 2021, the ANDA first filer, Dr. Reddy, was granted tentative approval of its 180-day exclusivity. ¶ 323, 359. This would have allowed Natco/Breckinridge, Aurobindo, and the other first filers to retain their 180-day exclusivity.

amount to a reverse payment: "only when alleged as 'part of' an otherwise unlawful reverse payment have such clauses triggered antitrust scrutiny." Celgene insists that is not the case here.

First, while the FAC does not directly identify any particular MFE or acceleration clauses, Celgene asserts that the provisions that Plaintiffs "appear to refer to" are "the same provisions that were at issue in *Actos*, and determined not to constitute reverse payments."[62] In *Actos*, the plaintiffs alleged that settlement agreements between the brand manufacturer and licensed generics contained an acceleration clause which ensured that if a generic—including an authorized generic—began marketing its product before the agreed upon entry date within the settlement agreement, the licensed generic could also enter at that earlier date, without further delay. *Actos*, 2015 WL 5610752, at *15. The court held that "the practical effect of the acceleration clauses was thus to increase competition in the event that other generics entered the market earlier than contemplated by the agreement. If no other generic entered before the licensed entry date, the effect would be neutral." *Id.* Here, as in *Actos*, the referenced MFE settlement terms provide for "a compromise date of generic entry" that are "the very type of settlement sanctioned by the *Actavis* Court." *Actos*, 2015 WL 5610752, at *14.

In response, Plaintiffs first ask that the Court consider two cases that have been decided since *Actos*, for the proposition that the acceleration clauses within the Pomalyst settlements are unlawful reverse payments. But those cases are based on distinct legal theories and do not support their assertions. In *In re Xyrem,* the disputed settlement agreement was a "no authorized generic" ("no-AG") agreement where the brand name

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[62] The November 2020 Celgene-Natco/Breckinridge agreement licensed Natco/Breckinridge to pre-expiration use of Celgene's patents, *i.e.,* licensed Natco/Breckinridge to enter the generic market for Pomalyst before the expiration of Celgene's patents, [redacted]. ¶ 314. The March 2021 Celgene-Teva agreement licensed Teva to use Celgene's patents [redacted]. ¶ 346. The July 2021 Celgene-Aurobindo agreement licensed Aurobindo to use Celgene's patents beginning [redacted]. ¶ 353. Due to the acceleration clauses, all ANDA first filers are licensed to pre-expiration use of Celgene's patents no later than the earliest of these dates, *i.e.*, [redacted]. Doc. 109 at 17.

settled exclusively with one generic and agreed not to market its own generic drug—or to grant a license to other companies to market an authorized generic—thereby limiting competition to just one generic drug. *In re Xyrem Antitrust Litigation*, 555 F. Supp. 3d 829, 850, 852 (N.D. Cal. 2021); *see also Actos*, 2015 WL 5610752, at *18. Similarly, in *In re Loestrin,* plaintiffs disputed four marketing or sales "promotional" agreements contained within a larger no-AG agreement, where the promotional services related to four separate drugs. *In re Loestrin 24 Fe Antitrust Litigation*, 261 F. Supp. 3d 307, 334–37 (D.R.I. 2017). However, these cases are not conflict with *Actos*, where the court considered and ultimately rejected Plaintiffs' arguments. *Actos*, 2015 WL 5610752, at * 18. Specifically, the *Actos* court held that "in stark contrast" to the instant scenario, acceleration clauses within no-AG agreements "trigger antitrust scrutiny due to their potential anticompetitive effect." *Id.*

Next, Plaintiffs argue that the Pomalyst settlement agreements also contain MFEP clauses. They allege that MFEP clauses "go further than MFE clauses, "guaranteeing [ANDA first filers] the best deal; the right to enter [the generic market] before [*non* ANDA first filers].[63] *Id.* (citing *Gilead*, 446 F. Supp. 3d at 612 (emphasis in original) ("a [most favored entry plus] clause guarantees a second filer that it will be in a *worse* position compared to the [ANDA] first filer even where there is no ANDA Exclusivity.")). However, Plaintiffs' cited cases do not support a finding that an MFEP clause can constitute a stand-alone reverse payment. As discussed above, the court in *Gilead* held that the MFEP clause could constitute a reverse payment because it "resurrect[ed]" an already forfeited 180-day ANDA exclusivity, which is not the case here. *Gilead*, 446 F. Supp. 3d at 612. As even Plaintiffs appear to concede, other courts have found that an acceleration clause *may* trigger antitrust scrutiny *only when* alleged as 'part of' an otherwise unlawful reverse payment. Doc. 127 at 36 (emphasis added).

[63] Non ANDA first filers refers to any generic manufacturer that files for an ANDA after the ANDA first filers, and is therefore not eligible for 180-day exclusivity.

Here, Plaintiffs have not sufficiently pleaded an unlawful reverse payment. Accordingly, the Court finds that Plaintiffs have failed to plausibly allege that the acceleration clauses constituted part of a reverse payment.

Accordingly, Plaintiffs have not plausibly alleged that the challenged settlement provisions—containing early entry licenses to the generic manufacturers and simultaneously timed early entry dates (*i.e.*, acceleration clauses)—constitute unlawful reverse payments. Further, Plaintiffs have not plausibly alleged that the challenged Pomalyst settlements protected profits in the market for Revlimid or how any such protection amounted to a payment.

Given that Plaintiffs have not plausibly alleged an unlawful reverse payment, the Court does not consider whether the alleged payment was "large" or "unexplained."

4. State Law Claims

Plaintiffs bring state law claims under the antitrust laws of 32 states and the District of Columbia.[64] ¶¶ 415–445, 460–472. In particular, they allege claims for: monopolization under the laws of 28 states and the District of Columbia; unjust enrichment under the laws of 28 states and the District of Columbia; and violations of consumer protection laws in 24 states and the District of Columbia. *Id*. Because the Court dismisses the federal antitrust claims, however, Plaintiffs' state law claims—based on the same factual allegations—fail too. *In re Bystolic Antitrust Litigation*, 583 F. Supp. 3d 455, 497 (S.D.N.Y. 2022), *aff'd sub nom. Watson Laboratories, Inc.*, 101 F.4th 223 (2d Cir. 2024) (citing *In re Tamoxifen Citrate Antitrust Litigation*, 277 F. Supp. 2d 121, 139 (E.D.N.Y. 2003) ("[S]ince Plaintiffs fail to state a claim under the Sherman Act, and since the state antitrust law claims are based on the same allegations, those claims are

[64] The 32 states include: Arizona, California, Connecticut, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin. ¶¶ 415–445, 460–472.

also dismissed.")); *see also In re Humira Antitrust Litigation*, 465 F. Supp. 3d 811, 847 (N.D. Ill. 2020).

B. Insogna

Plaintiffs next allege claims against Anthony Insogna for monopolization pursuant to Section 2 of the Sherman Act and its state law analogues. ¶¶ 67, 446–472. Specifically, they assert that Insogna "orchestrated Celgene's scheme to fraudulently obtain patents and was an integral component of the overarching monopolization scheme." In response, Insogna asserts that Plaintiffs have failed to state a claim and that their claims are time-barred.[65]

As alleged in the FAC, Insogna's participation in the monopolization scheme is based solely on his conduct as outside patent counsel representing Celgene before the PTO. ¶¶ 67, 446–472. However, because the Court holds that Plaintiffs lacks antitrust standing to bring *Walker Process* fraud claims against Celgene, and that Plaintiffs have otherwise failed to sufficiently plead *Walker Process* fraud, the Court holds that Plaintiffs' allegations against Insogna similarly fail.

C. Zeldis

Plaintiffs next allege monopolization under state law against defendant Jerome Zeldis.[66] Zeldis asserts that Plaintiffs (1) have failed to state a claim for monopolization against him, (2) lack personal jurisdiction over him, and (3) are time-barred from pursuing their claims.

As with Insogna, because the Court holds that Plaintiffs lack antitrust standing to bring *Walker Process* fraud claims against Celgene, and that Plaintiffs have otherwise

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[65] Insogna asserts that "the claims … should also be dismissed for the reasons stated in Celgene's contemporaneously filed briefing as well as Parts II and III of [] Zeldis'' contemporaneously filed briefing." Doc. 130 at 2 n.1.

[66] In the FAC, Plaintiffs bring Count IV, unlawful monopolization under Section 2 of the Sherman act, requesting declaratory and injunctive relief against Zeldis. ¶¶ 446–459. However, in their opposition to the instant motion they "concede [that] there is no injunctive and declaratory relief available to them from Zeldis under Section 2 of the Sherman and Act" and withdraw that claim. Doc. 127 at 45.

failed to sufficiently plead *Walker Process* fraud, the Court holds that Plaintiffs' allegations against Zeldis similarly fail. Even assuming, *arguendo,* that Plaintiffs had standing to bring their *Walker Process* claims and that they were sufficiently pleaded, the Court would still dismiss for lack of personal jurisdiction.

1. Personal Jurisdiction

Zeldis, who is domiciled in Florida, argues that he is not subject to personal jurisdiction in New York. Courts evaluating personal jurisdiction over foreign defendants take a two-step approach. First, the Court must determine if jurisdiction exists under the law of the forum state. In this case, the Court must first determine whether personal jurisdiction is appropriate pursuant to New York State's long-arm jurisdiction statute, C.P.L.R. § 302(a). Second, the Court will then evaluate whether the exercise of personal jurisdiction comports with the Fifth Amendment Due Process Clause of the United States Constitution. *Queen Bee of Beverly Hills*, *LLC*, 616 F.3d at 164.

Plaintiffs allege that personal jurisdiction over Zeldis is proper under C.P.L.R. § 302(a)(1). This provision permits the exercise of specific jurisdiction over a nondomiciliary if the defendant "transacts any business within the state[.]" C.P.L.R § 302(a)(1). Under § 302(a)(1), a court examines "(1) whether the defendant 'transacts any business' in New York and, if so, (2) whether this cause of action 'aris[es] from' such a business transaction." *Best Van Lines, Inc. v. Walker*, 490 F.3d 239, 246 (2d Cir. 2007) (alteration in original) (citation omitted). Transacting business is defined as purposeful activity, meaning "some act by which the defendant purposefully avails [himself] of the privilege of conducting activities within the forum state, thus invoking the benefits and protections of its laws." *Best Van Lines*, 490 F.3d at 246 (citation omitted). "New York courts have held that a claim aris[es] from a particular transaction when there is some articulable nexus between [the] business transacted and the cause of action sued upon." *Solé Resort, S.A. de C.V. v. Allure Resorts Management, LLC*, 450 F.3d 100, 103 (2d Cir. 2006) (internal quotation marks and citation omitted). Section 302(a)(1) is a "single act" statute, meaning

"a single transaction of sufficient quality may invoke jurisdiction, provided that the transaction was purposeful, and the necessary relationship between the transaction and the claim asserted exists." *Rich v. Fox News Network, LLC*, No. 18-cv-2223 (GBD), 2020 WL 6276026, at *3 (S.D.N.Y. Sept. 15, 2020). Additionally, when a defendant makes remote communications that "effectuate some purposeful business in New York," personal jurisdiction pursuant to § 302(a)(1) "will be found even if a defendant never actually entered the state." *Fox News Network, LLC*, 2020 WL 6276026, at *3 (citing *Pickett v. Migos Touring, Inc.*, 420 F. Supp. 3d 197, 204 (S.D.N.Y. 2019)).

In support of their claim, Plaintiffs point to the New York connections described in Zeldis' declaration which they argue suggests that he had continuous and systematic contact with New York during his employment with Celgene from 1997 to 2016, sufficient to satisfy the first step of the analysis under the New York long arm statute § 302(a)(1).[67] In his declaration, Zeldis describes being a Clinical Associate Professor of Medicine at Cornell Medical School from 1995 to 2003, and owning a series of apartments in New York, the first of which was purchased in 2008. ¶¶ 2, 11–17. Plaintiffs argue that given the length of his tenure at Cornel Medical School, his ownership of apartments in New York City, and the proximity of Celgene's headquarters in New Jersey to New York City, "it is . . . likely" that Zeldis transacted business on Celgene's behalf—such as fielding phone calls, attending meetings, and potentially overseeing clinical trials—while in New York.

[67] In their proposal for limited jurisdiction discovery Plaintiffs also pointed to Celgene's attorneys, the law firm Pennie & Edmonds, who filed the Provisional Patent Application naming Zeldis as the inventor, from their New York office. Doc. 147 at 3. They argued that they had made a *prima facie* showing of personal jurisdiction over Zeldis or, at a minimum, had articulated a colorable basis for personal jurisdiction because (1) "Zeldis conducted business within the state … as named inventor and signatory, seeking fraudulent patents through New York law firms over the course of more than a decade[], and, (2) that business gave rise to the claims [.]" *Id.* However, in its July 9, 2024, Order, the Court determined that "the fact that Zeldis was listed as the inventor on patents belonging to Celgene—headquartered in New Jersey—and filed in Virginia, by a New York based law firm, without more [was] "simply too tenuous of a connection to New York." Doc. 147 at 6 (citing *Haussmann, Trustee of Konstantin S. Haussmann Trust v. Baumann*, 73 Misc. 3d 1234(A), 157 N.Y.S. 3d 355, 2021 WL 6110467 (Sup. Ct., New York Cnty., Dec. 27, 2021); Doc. 137 at 1).

However, as held in the July 9, 2024 Order, "these instances, individually and combined, only lead to 'speculation that [] jurisdiction could exist based on speculation that he could have transacted business giving rise to their claims while in New York.'" As held there, Plaintiffs provide no support for the assertion that the proximity of Celgene's headquarters in New Jersey to New York City supports specific jurisdiction over Zeldis in New York. Additionally, although Zeldis had an apartment in New York City, from 2008 until 2010 it was being rented by his daughter, from 2010 until December 2011 it was being leased to renters, and went "generally unoccupied" until 2014, according to Zeldis. The fact that Zeldis would reside there one or two weekends per month between December 2011 and 2014, provides no basis to infer that he conducted any business in New York at all, much less that he conducted work specifically related to the issues in the case. *Id.* at 14. This too could be said for his work at Cornell Medical School; being employed in the State as a clinical professor is insufficient alone to infer that he conducted work relating to the specific patents or applications. Therefore, Plaintiffs have failed to plausibly plead that the court has personal jurisdiction over Zeldis.

Accordingly, because Plaintiffs lack antitrust standing to bring *Walker Process* fraud claims against Zeldis and because the Court otherwise lacks jurisdiction over him, Zeldis' motion to dismiss the complaint is GRANTED.

IV. CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss are GRANTED for failure to state a claim pursuant to Section 2 of the Sherman Act, and analogous state law claims. Zeldis' motion to dismiss is also GRANTED for lack of personal jurisdiction. The Clerk of Court is respectfully directed to terminate the motions, Docs. 108, 113, 117, and 120, and close the case.

It is SO ORDERED.

Dated: March 31, 2025
New York, New York

EDGARDO RAMOS, U.S.D.J.